Department of Health and Human Services DEPARTMENTAL APPEALS BOARD Appellate Division

Consolidated Home Health Docket No. A-17-126 Decision No. 2878 June 27, 2018

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Petitioner Consolidated Home Health (Consolidated), a Medicare home health agency (HHA) based in Missouri, appeals an Administrative Law Judge's (ALJ's) decision sustaining the determinations of the Centers for Medicare & Medicaid Services (CMS) to terminate Consolidated's participation in the Medicare program and impose civil monetary penalties (CMPs) of \$8,500 per day for the period of August 7 through August 30, 2015 (\$204,000 total). *Consolidated Home Health*, DAB CR4923 (2017) (ALJ Decision). CMS imposed those sanctions after two surveys in August 2015 found that Consolidated was not in compliance with six conditions of participation for HHAs and that noncompliance with one condition relating to patient care posed immediate jeopardy. The ALJ addressed that condition of participation and concluded that Consolidated was not in compliance posed immediate jeopardy, and that Consolidated failed to timely attain compliance or remove the immediate jeopardy, warranting the sanctions CMS imposed.

As explained below, we affirm the ALJ Decision and sustain the termination and CMPs imposed by CMS.

Relevant Legal Authorities

HHAs that participate in the Medicare and Medicaid programs must meet conditions of participation in section 1891 of the Social Security Act (Act) and 42 C.F.R. Part 484 and their subsidiary standards in the regulations.¹ The conditions of participation are found in subparts B and C of Part 484 and contain requirements for the various services an HHA

¹ The current version of the Act can be found at http://www.socialsecurity.gov/OP_Home/ssact/ssact-toc.htm. Each section of the Act on that website contains a reference to the corresponding United States Code chapter and section. Also, a cross-reference table for the Act and the United States Code can be found at http://uscode.house.gov/table3/1935_531.htm and https://www.ssa.gov/OP_Home/comp2/G-APP-H.html.

must provide and standards for its operations. Each condition of participation is contained in a single regulation, which is divided into subparts called standards of participation.² *See* 42 C.F.R. §§ 484.10-484.55.

CMS determines HHA compliance with these requirements through unannounced surveys performed by state agencies under agreements with CMS. 42 C.F.R. §§ 488.10-488.12; 488.18-.26; subpart I (488.700-.745, "Survey and Certification of Home Health Agencies"). If a "standard survey" finds an HHA "was out of compliance with a condition of participation[,]" then the state agency conducts an "extended survey." 42 C.F.R. § 488.720(b). Compliance with a condition of participation is determined by the manner and degree to which the provider satisfies the standards within the condition. Id. § 488.26(b); CSM Home Health Servs., Inc., DAB No. 1622, at 6-7 (1997). If standardlevel deficiencies are of such character as to "substantially limit the provider's ... capacity to furnish adequate care or . . . adversely affect the health and safety of patients[,]" the provider is not in compliance with a condition of participation. 42 C.F.R. § 488.24(b). A "[s]tandard-level deficiency means noncompliance with one or more of the standards that make up each condition of participation for HHAs." Id. § 488.705. A "[c]ondition-level deficiency means noncompliance as in § 488.24" which in turn refers to "compliance with the conditions of participation or conditions for coverage where the deficiencies are of such character as to substantially limit the provider's or supplier's capacity to furnish adequate care or which adversely affect the health and safety of patients...." Id. §§ 488.705, 488.24(b).

CMS may impose sanctions, including CMPs and termination of an HHA's Medicare participation, "on the basis of noncompliance with one or more conditions of participation found through a survey" 42 C.F.R. §§ 488.810(b); 488.820 (listing available sanctions); *see* Act § 1891(e), (f). When CMS determines that noncompliance by an HHA poses immediate jeopardy to patients, the regulations provide for the following actions:

Immediate jeopardy. If there is immediate jeopardy to the HHA's patient health or safety -

(1) CMS immediately terminates the HHA provider agreement in accordance with § 489.53 of this chapter.

² Effective July 13, 2017, CMS revised the conditions of participation in Part 484 that HHAs must meet to participate in the Medicare and Medicaid programs. Final Rule, *Medicare and Medicaid Program: Conditions of Participation for Home Health Agencies*, 82 Fed. Reg. 4504, 4578 (Jan. 13, 2017). We rely on the regulations in effect when the state agency performed the surveys, which are the regulations that formed the bases for CMS's determination of noncompliance and the ALJ Decision. *Carmel Convalescent Hosp.*, DAB No. 1584, at 2 n.2 (1996) (Board applies the regulations in effect on the date of the survey and resurvey).

(2) CMS terminates the HHA provider agreement no later than 23 days from the last day of the survey, if the immediate jeopardy has not been removed by the HHA.

(3) In addition to a termination, CMS may impose one or more alternative sanctions, as appropriate.

Id. § 488.825(a). If immediate jeopardy is not present, "CMS terminates an HHA within 6 months of the last day of the survey, if the HHA is not in compliance with the conditions of participation, and the terms of the plan of correction have not been met." *Id.* § 488.830(d); *see* § 488.810(e) (requiring an HHA facing sanctions to "submit a plan of correction," or "POC," for approval by CMS). "Immediate jeopardy" is "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 patient(s)." *Id.* § 488.805.

Available alternative sanctions include CMPs. *Id.* § 488.820. CMS may impose a CMP "for either the number of days the HHA is not in compliance with one or more conditions of participation or for each instance that an HHA is not in compliance, regardless of whether the HHA's deficiencies pose immediate jeopardy." *Id.* § 488.845(a). For "a condition-level deficiency that is immediate jeopardy," which the ALJ found here, CMPs "in the upper range of \$8,500 to \$10,000 . . . per day of noncompliance are imposed" and "will continue until compliance can be determined based on a revisit survey."³ *Id.* § 488.845(b)(3). Within that range, CMS imposes "(i) \$10,000 . . . per day for a deficiency or deficiencies that are immediate jeopardy and that result in actual harm"; "(ii) \$9,000 . . . per day for a deficiencies that are immediate jeopardy and that result in a potential for harm"; and "(iii) \$8,500 . . . per day for an isolated incident of noncompliance in violation of established HHA policy." *Id.*

The regulations set out factors CMS takes into account in determining the amount of the penalty including, as relevant here, an HHA's size and resources; evidence that it has a built-in, self-regulating quality assessment and performance management system; the extent to which deficiencies pose immediate jeopardy; the nature, incidence, manner, degree, and duration of deficiencies or noncompliance; the agency's overall compliance history and the presence of repeat deficiencies; the extent to which deficiencies are directly related to the failure to provide quality patient care; the extent to which an agency is part of a larger organization with performance problems; and, an indication of

³ A "middle range" CMP of \$1,500-\$8,500 and a "lower range" CMP of \$500-\$4,000 per day is imposed for "a repeat and/or condition-level deficiency that does not constitute immediate jeopardy" but "is directly related to poor quality patient outcomes" or is "related predominantly to structure or process-oriented conditions," respectively. A "Per instance" CMP of \$1,000-\$10,000 "may be assessed for one or more singular events of condition-level noncompliance that are identified and where the noncompliance was corrected during the onsite survey." *Id.* § 488.845(b)(4)-(6).

any system-wide failure to provide quality care. 42 C.F.R. §§ 488.845(b)(1), 488.815(a)-(f).

The termination of an HHA's provider agreement and the imposition of CMPs are "initial determinations" by CMS that an HHA may appeal through an ALJ hearing, "but not the determination as to which sanction was imposed." *Id.* § 498.3(b)(13). An HHA may also challenge CMS's determination of the HHA's level of noncompliance, "but only if a successful challenge on this issue would affect— . . . [t]he range of civil money penalty amounts that CMS could collect[.]" *Id.* § 498.13(b)(14).

On review, the ALJ and the Board may not reduce a CMP to zero, review "the exercise of discretion by CMS to impose a civil monetary penalty;" or consider "any factors in reviewing the amount of the penalty other than those specified" in § 488.845(b). *Id.* § 488.845(h). CMS' determination "as to the level of noncompliance" of an HHA – whether it poses immediate jeopardy – "must be upheld unless it is clearly erroneous." 42 C.F.R. § 498.60(c).

Case Background⁴

The state agency, the Missouri Department of Health and Senior Services, conducted an extended survey of Consolidated from August 3-7, 2015. The state agency determined that Consolidated was not in compliance with six conditions of participation (six "condition-level deficiencies"), and that Consolidated's noncompliance with one condition relating to the care of patients posed immediate jeopardy to patient health and safety. ALJ Decision at 3 (citing CMS Exs. 1 (Statement of Deficiencies, or SOD); 4 (termination notice); 11 at ¶ 5 (surveyor decl.));⁵ see CMS Ex. 3 (CMS Aug. 12, 2015 termination letter).

The ALJ and CMS exclusively addressed the sole condition-level deficiency that posed immediate jeopardy and related standard-level deficiencies under that condition. ALJ Decision at 14; CMS Pre-Hearing Br. at 5. That condition, at 42 C.F.R. § 484.18, "Condition of participation: Acceptance of patients, plan of care, and medical supervision," requires that "Patients are accepted for treatment on the basis of a reasonable expectation that the patient's medical, nursing, and social needs can be met adequately by the agency in the patient's place of residence" and that "Care follows a written plan of care established and periodically reviewed by a doctor of medicine, osteopathy, or podiatric medicine." 42 C.F.R. § 484.18. Section 484.18 then states in

⁴ This background is based on the ALJ Decision and the record below and is not intended as new factual findings. We discuss and resolve any relevant factual disputes in our analysis below.

⁵ The ALJ cited "CMS Ex. $10 \$ f"," but clearly intended to cite CMS Exhibit 11 at f" 5. CMS Exhibit 10 comprises 446 pages of survey notes and documentation from the revisit survey ending August 28, 2015.

relevant part as follows:

(a) Standard: Plan of care. The plan of care developed in consultation with the agency staff covers all pertinent diagnoses, including mental status, types of services and equipment required, frequency of visits, prognosis, rehabilitation potential, functional limitations, activities permitted, nutritional requirements, medications and treatments, any safety measures to protect against injury, instructions for timely discharge or referral, and any other appropriate items. . . .

(b) Standard: Periodic review of plan of care. The total plan of care is reviewed by the attending physician and HHA personnel as often as the severity of the patient's condition requires, but at least once every 60 days or more frequently when there is a beneficiary elected transfer; a significant change in condition resulting in a change in the case-mix assignment; or a discharge and return to the same HHA during the 60-day episode. Agency professional staff promptly alert the physician to any changes that suggest a need to alter the plan of care.

(c) Standard: Conformance with physician orders. Drugs and treatments are administered by agency staff only as ordered by the physician

42 C.F.R. § 484.18.

The state agency determined that Consolidated was not in compliance with this condition and its three standards (§ 484.18(a), (b), (c)), and that the noncompliance comprised one condition-level deficiency and five standard-level deficiencies. ALJ Decision at 3; CMS Ex. 1, at 16-40. The state agency based the condition-level deficiency on the five standard-level deficiencies, which concern failure to meet the specific requirements in the overarching, introductory language of section 484.18 and in the three conditions in paragraphs (a), (b), and (c). *Id*.

The survey addressed Consolidated's care of six patients, designated as Patients #1-#5 and #8. The survey found that Consolidated failed to ensure: (1) that it accepted patients "on expectation that the patient's medical, nursing, and social needs can be adequately met . . . in the patient's home"; (2) that its staff "follow[ed] the written plan of care as ordered by the physician"; (3) that it developed "a complete and accurate plan of care for each patient receiving home health services"; (4) that its staff "promptly alert[ed] the physician to any changes that suggest a need to alter the plan of care"; and (5) that "drugs and treatments [were] administered by agency staff only as ordered by the physician." ALJ Decision at 3, 7; CMS Ex. 1, at 16.

Following the survey, CMS informed Consolidated by notice of August 12, 2015 that its Medicare provider agreement would be terminated effective August 30, 2015, that CMS would impose a CMP of \$8,500 per day, and that Consolidated could avert the termination by showing that it had corrected the immediate jeopardy pursuant to an approved plan of correction (POC) showing (among other requirements) when it completed the correction. ALJ Decision at 3-4; CMS Ex. 3. Consolidated filed a POC alleging that it would correct the immediate-jeopardy noncompliance by August 21, and the state agency conducted a resurvey on August 27 and 28, 2015 that focused on the immediate-jeopardy level condition-level deficiency and the related standard-level deficiencies. ALJ Decision at 4; CMS Ex. 2 (SOD from survey ending Aug. 28, 2015).

The resurvey found that Consolidated had not corrected the condition-level deficiency (and related standard-level deficiencies) that continued to pose immediate jeopardy, and that Consolidated had not corrected the remaining five condition-level deficiencies. ALJ Decision at 4 (citing CMS Exs. 2, and 12 at ¶¶ 10-13). CMS then informed Consolidated by notices of August 28 and September 9, 2015 that its Medicare provider agreement would be terminated on August 30, 2015 and that CMS was imposing the \$8,500 per-day CMP for the period August 7 through August 30, 2015 (total \$204,000). *Id.* (citing CMS Exs. 4, 5).

Consolidated requested an ALJ hearing to dispute only CMS's immediate jeopardy determination. *See* Request for Hearing at 2 ("[W]e do not believe that the deficiencies that we were cited for, were serious enough to cause immediate jeopardy to the patients [and we] request that the IJ citation be removed and we be compensated for our resulting los[s]es."). Consolidated filed a pre-hearing brief (P. Br.) and 38 exhibits (P. Exs. 1-38) and CMS filed a pre-hearing brief (CMS Br.) and 12 exhibits (CMS Exs. 1-12), all of which the ALJ admitted absent objection. ALJ Decision at 4-5. Consolidated requested that the ALJ issue a decision on the record without holding a hearing, and CMS did not object. *Id.* at 5. The parties in their briefs addressed only the noncompliance with section 484.18.

ALJ Decision

I. The ALJ found that Consolidated did not comply with the condition of participation at section 484.18 in its care of five patients, and that the noncompliance posed immediate jeopardy.

The ALJ found that Consolidated did not comply with the condition of participation at section 484.18 in its care of five home health patients (Patients #1-#5), and made the following numbered findings of fact and conclusion of law (FFCLs). First, the ALJ made the overarching determination that Consolidated "was not in substantial compliance with the condition of participation required by 42 C.F.R. § 484.18," which "amounted to immediate jeopardy," and "did not return to compliance before termination of its provider

agreement" (FFCL #1). ALJ Decision at 5. The ALJ based FFCL #1 on the following determinations (FFCLs #1.a and #1.b).

The ALJ determined that Consolidated, in its care of Patients #1 and #5, "failed to comply" with the overarching requirement in 42 C.F.R. § 484.18 that "[p]atients are accepted for treatment on the basis of a reasonable expectation that the patient's medical, nursing, and social needs can be met adequately by the agency in the patient's place of residence" (FFCL #1.a). *Id.* at 6. Consolidated had accepted Patients #1 and #5 for care but could not show that it provided, or was able to provide, the services they required, and "did not address or specifically dispute these issues in its brief[.]" *Id.* at 6-7.

The ALJ then found that Consolidated, in its care of all five patients, failed to comply with the further requirement in the overarching, introductory language of section 484.18 that "[c]are . . . follows a written plan of care established and periodically reviewed by a doctor of medicine, osteopathy, or podiatric medicine" (FFCL #1.b). *Id.* at 7-12. Under FFCL 1.b, the ALJ focused primarily on Patient #3, finding that Consolidated placed the patient at risk of "serious harm due to blood clots" by "[a]llowing Patient #3 to be without the prescribed Lovenox," an injectable blood thinning/anticoagulant medication, "for five days following a stay in the hospital without contacting Patient #3's physician." *Id.* at 8, 10-12. Patient #3 had been discharged from the hospital on July 7, 2015, had a primary diagnosis of acute venous embolism and deep vein thrombosis (DVT) with a "fair" prognosis, and began receiving home health services from Consolidated on July 9, 2015. *Id.* at 8.

Patient #3's care plan called for one blood thinning/anticoagulant medication (Warfarin) by mouth daily and for Lovenox by injection twice a day, but the Lovenox had not been delivered to the patient's home when Consolidated's nurse arrived on July 9, and it was not delivered until July 13, 2015. During that time, the ALJ found, the nurse did not call the prescribing hospital physician or the patient's personal physician, which constituted noncompliance that posed immediate jeopardy. *Id.* at 8-12.

The ALJ rejected the nurse's undocumented contention that she called the hospital physician about the lack of Lovenox on July 9 but did not hear back, and the nurse's apparent position that it was the hospital's responsibility to assure that Lovenox was timely delivered to the patient's home, since the hospital had ordered the medication from the pharmacy. *Id.* at 10-11. The ALJ found the nurse's failure to document the alleged phone call "at variance with her detailed documentation of her calls to Patient #3 concerning the patient's efforts to obtain Lovenox, and her call on July 14, 2015, to Patient #3's physician." *Id.* at 11. The ALJ further found that the nurse "manifests a view that it was the hospital's responsibility to deal with the failure of the pharmacy to timely deliver the Lovenox, indicating it is more likely that she took no action when the Lovenox was not present for her to inject into Patient #3 on July 9, 2015." *Id.* The ALJ also found that the nurse "seemed unconcerned that Patient #3 ultimately had to inject the

Lovenox by himself, without her instruction or supervision, because the hospital supposedly trained Patient #3," and that "[r]egardless as to any alleged instruction by the hospital, Patient #3 injecting himself with the medication without the nurse present was a violation of the care plan." *Id*.

The ALJ accordingly rejected Consolidated's argument that the nurse contacted the hospital physician instead of the patient's personal physician because, according to Consolidated, the personal physician did not know about the order for Lovenox. *Id*. The ALJ found that the nurse should have contacted Patient #3's personal physician because the patient "was in danger from his DVT condition," and the nurse "was the only health care provider on the scene to coordinate his care under the care plan, which was in fact her job as a home health nurse." *Id*. The ALJ rejected Consolidated's argument that the nurse "did all she could under the circumstances with the exception that she did not document her call to" the hospital physician as showing "a complete lack of responsibility for the patient that Petitioner had under its care." *Id*. (citing P. Br. at 5-6). The ALJ accordingly concluded that Consolidated "failed to comply with the plan of care related to Patient #3 and did not substantially comply with § 484.18." *Id*.

The ALJ further concluded that "the evidence of record supports that Petitioner placed Patient #3 in immediate jeopardy," because "[a]llowing Patient #3 to be without the prescribed Lovenox for five days following a stay in the hospital without contacting Patient #3's physician could have resulted in serious harm due to blood clots" and that the patient "was in grave danger from DVT" *Id.* at 10, 12. The ALJ cited information from the Mayo Clinic website that CMS quoted in its brief that DVT "occurs when a blood clot (thrombus) forms in one or more of the deep veins in your body, usually in your legs" and is "a serious condition because blood clots in your veins can break lo[o]se, travel through your bloodstream and lodge in your lungs, blocking the blood flow (pulmonary embolism)." *Id.* at 9 (citing CMS Br. at 8-9 n.3 (citing Mayo Clinic Patient Care & Health Information)).⁶ The ALJ also cited the declaration of a state agency nurse surveyor that DVT "carries great risk to a patient's health and must be treated and monitored properly." *Id.* (citing CMS Ex. 11, at 2).

Under FFCL 1.b, the ALJ also addressed Patients #1, #2, #4 and #5. For each, the ALJ found that Consolidated failed to follow or comply with each patient's care plan and thus did not "substantially comply with § 484.18." *Id.* at 7-8, 12. For Patients #1, #2, and #4, the ALJ found that Consolidated failed to provide the number of skilled nursing visits per week ordered in their care plans. *Id.*

⁶ https://www.mayoclinic.org/diseases-conditions/deep-vein-thrombosis/symptoms-causes/syc-20352557.

For Patient #5, the ALJ found that Consolidated failed to follow orders in the care plan for providing oxygen, checking oxygen levels during care, and weighing the patient daily, and that the surveyor observed that "the patient became visibly short of breath" when bathed without oxygen. The ALJ concluded that Consolidated "failed to comply with the plan of care for Patient #5 and failed to substantially comply with § 484.18" and that "the evidence of record supports that Petitioner placed Patient #5 in immediate jeopardy." *Id.* at 12.

II. The ALJ found that as of the revisit survey Consolidated remained out of compliance with section 484.18 and that it was unnecessary to address other noncompliance findings under section 484.18.

Under FFCL 1.b, the ALJ also concluded that as of the revisit survey ending August 28, 2015, Consolidated "failed to comply with its own plan of correction" and "remained out of compliance" with the requirement in section 484.18 that care provided to the patient follows a written plan of care established and periodically reviewed by a doctor of medicine, osteopathy, or podiatric medicine. *Id.* at 13-14.

The ALJ noted that the POC called for a Quality Improvement (QI) nurse to review or audit "all active charts and discharges 'with the newly updated QI tool[]" and to review "patient status, services provided, and medications and discussion of interim orders written during the week [and] all discipline notes" and "notify staff members of missing paperwork" so they could submit corrections "immediately." *Id.* at 13 (citing CMS Ex. 7, at 2). Consolidated committed to complete these corrective actions by August 21, 2015. *Id.* Yet, as of the resurvey, only three charts had been reviewed or audited, one by the director of nursing (DON) and two "by a staff nurse who was helping out in the evening." *Id.* (citing CMS Ex. 2, at 9).

The ALJ also credited surveyor revisit observations of "multiple instances" of nurses failing to follow "proper infection control and standard precautions" for Patients #1 and #2, placing them "at risk for contamination and infection." *Id.* (citing CMS Ex. 2, at 11-23). For Patients #1 and #2, the ALJ found Consolidated did not dispute that during the revisit survey, the nurses "failed to comply with physician orders to implement standard infection control precautions and to treat and dress [Patient #1's] wounds," and failed "to follow the physician's order to implement standard infection control precautions" for Patient #2. *Id.* at 7-8.

Finally, the ALJ found that Consolidated had not provided its staff "sufficient training" on DVT as it had promised in the POC. *Id.* at 13-14. The ALJ credited the nurse surveyor's opinion that the training seemed to consist of nothing more than distribution of a 19-page document about DVT from the Merck Manual website with no effort to "go over" the document with staff (including the DON) who, when questioned, appeared to have retained little knowledge or understanding of the subject. *Id.* (citing CMS Ex. 12, at

2-3). The ALJ credited the nurse surveyor's statement over the DON's, on the ground that the surveyor nurse's "testimony was detailed while Petitioner's evidence less clear." *Id.* at 14.

The ALJ then found he did not need to review the other deficiencies alleging noncompliance with section 484.18 "in order to sustain the sanctions CMS imposed" because the noncompliance he found above was "sufficient to show Petitioner's noncompliance with the entire condition of participation" and that "some of Petitioner's noncompliance was at the immediate jeopardy level" (FFCL 1.c). *Id*.

III. The ALJ sustained the \$8,500 per-day CMP and the termination.

The ALJ found the \$8,500 per-day CMP "authorized under the applicable regulations" (FFCL 2), noting that the regulations impose "CMPs in the upper range of \$8500 to \$10,000 per day for a condition-level deficiency that constitutes immediate jeopardy," with the \$8,500 per day CMP "meant for an isolated incident of noncompliance." Id. at 14-15 (citing 45 C.F.R. § 488.845(b)(1), (3)). The ALJ did not accept Consolidated's argument that the CMP should be reduced based on the regulatory factors. Consolidated asserted it had limited revenues and access to legal counsel, had a history of only onecondition level deficiency that it cured, was not part of a larger organization with performance problems, and had a self-regulating quality assessment and performance system. The ALJ noted that Consolidated did not argue that it did not have the financial resources to pay the CMP. The ALJ then found the per-day CMP "reasonable" because the deficiencies "posed immediate jeopardy [that] was not abated"; because "Petitioner's failure to implement its plan of correction and its repeated deficiencies at the revisit survey indicate that Petitioner's deficiencies were of such a character and extent that it affected its ability to provide quality patient care"; and because "[t]he surveyors found an agency that was in complete disarray; its records were chaotic and the DON did not appear to be able to effectively manage the agency." Id. at 15.

The ALJ then found that "CMS's imposition of termination was authorized under the applicable regulations" (FFCL #3). *Id.* The ALJ concluded that "CMS was authorized to terminate Petitioner's Medicare provider agreement" because Consolidated "was out of compliance with a condition of participation at the immediate jeopardy level and . . . did not return to compliance within the time stated by CMS." *Id.* at 16.

Standard of Review

We review a disputed finding of fact to determine whether the finding is supported by substantial evidence, and a disputed conclusion of law to determine whether it is erroneous. *See* Departmental Appeals Board, Guidelines for Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's Participation in the Medicare and Medicaid Programs, "Completion of the Review Process," ¶ (c), available

at https://www.hhs.gov/about/agencies/dab/different-appeals-at-dab/appeals-to-

<u>Analysis</u>

board/guidelines/participation/index.html.

On appeal, Consolidated argues that the ALJ erred in upholding any immediate jeopardy noncompliance findings from either survey and did not correctly apply the regulatory factors in upholding the per-day CMP that CMS imposed. Consolidated also acknowledges that before the ALJ, it challenged only the immediate-jeopardy noncompliance, argues that CMS's immediate jeopardy findings were limited to Patient #3 and that the ALJ erred in finding immediate jeopardy based on other patients, and presents argument and evidence on patients it did not address below.

As we discuss, Consolidated's arguments provide no basis to reverse the ALJ Decision.

I. Consolidated's arguments about Patient #3 provide no basis to reverse the ALJ's determination that Consolidated was not in compliance with the condition of participation, which is free of legal error and supported by substantial evidence.

Regarding Patient #3, Consolidated continues to assert that its nurse did call the hospital physician on July 9, 2015 about the missing Lovenox, and to blame the hospital for failing to ensure the medication's timely delivery. In support of those arguments, which the ALJ rejected, Consolidated now posits "that the hospital did not order the medication until the nurse called them on July 9th, 2015" because "it does not take 4 days (from July 7 to 11, 2015) for the Pharmacy to inform the Patient of the status" of the medication order.⁷ Request for Review (RR) at 5. This theory, Consolidated argues, "supports our belief that the nurse did make the call to the hospital on July 9th, 2015," although Consolidated does not explain why. *Id.* Consolidated also maintains that "the medical professionals at the hospital best understand the risk of the patient being without medication for a few days and should have ordered the medication on July 7th, 2015." *Id.* Consolidated argues that this immediate-jeopardy citation should not be based solely on the nurse's failure to document the call that Consolidated insists she did make to the hospital physician on July 9, 2015. *Id.* at 6.

Consolidated does not explain how its speculative theory that the hospital failed to order the medication, even if true, shows error in the ALJ Decision or supports its claim that its nurse called the hospital physician on July 9. It was the absence of the medication, regardless of the reason for the absence, which should have prompted Consolidated to

⁷ Consolidated stated below that on July 11, 2015, the pharmacy informed Patient #3 that the Lovenox would be delivered on July 13, 2015. RR at 5; *see* P. Br. at 4. The ALJ found that the nurse "communicated with Patient #3 during the [days] following" July 9, 2015 "but the medication was not delivered." ALJ Decision at 8.

notify the hospital physician who (it is not disputed) prescribed it, as well as the patient's personal physician, as the lack of the Lovenox undisputedly placed the patient at risk for blood clots. While the ALJ quoted the nurse surveyor's statement that delivery of the Lovenox was delayed "because the pharmacy was out," he based his finding of immediate-jeopardy noncompliance on the nurse's (and thus Consolidated's) failure to respond timely to the absence of the medication, without addressing the reason for its absence. ALJ Decision at 9.

The record, moreover, does not support Consolidated's theory that the hospital did not order the medication prior to discharging the patient on July 7, 2015. Consolidated posits that had the hospital ordered the Lovenox, the pharmacy would not have waited until July 11 to contact the patient about the medication. RR at 5. Below, Consolidated cited its nurse's notes recorded in a "Case Management Form" for Patient #3 as showing that the nurse "learned on July 11, 2015. . . that the Lovenox would be delivered on July 13 (Monday)." P. Br. at 4 (citing P. Ex. 11, at 2). The notes indicate, however, that the patient had been in contact with the pharmacy prior to July 11 and that delivery was delayed because the pharmacy was out of the medication, consistent with the surveyor's testimony. The notes state that the patient told the nurse on July 10 that the medication was to be delivered the next day and told her on July 11 that the medication was not available, and that the pharmacy stated it would be delivered on Monday (July 13, 2015). P. Ex. 11, at 2. This record provides no clear basis to find that the hospital failed to order Lovenox from the pharmacy.

The Board has long held that it will defer to an ALJ's findings on "weight and credibility of witness testimony (oral or written) unless there are 'compelling' reasons not to do so." *River City Care Ctr.*, DAB No. 2627, at 13 (2015), *aff'd*, *River City Care Ctr. v. U.S. Dep't of Health & Human Servs.*, 647 F. App'x 349 (5th Cir. 2016) (citing *Van Duyn Home & Hosp.*, DAB No. 2368, at 10-11 (2011) and *Koester Pavilion*, DAB No. 1750, at 16, 21 (2000)). The ALJ gave specific reasons for not crediting the nurse's statement that she called the hospital physician on July 9, and Consolidated has not addressed the ALJ's analysis on this point. Consolidated has not furnished compelling reasons for the Board not to defer to the ALJ's finding that the nurse failed to contact the hospital physician (or the patient's personal physician) when the needed medication had not been delivered to the patient's home on July 9, 2015.

Consolidated also disputes the ALJ's determination that Consolidated failed to implement the care plan by permitting Patient #3 to inject himself with the Lovenox after it was finally delivered on July 13, 2015. Consolidated asserts that the nurse "was assured by the Patient that he was trained by the hospital to administer and felt capable to do it" which "is not an uncommon occurrence and the Patient did not have an issue administering the medication." RR at 5 (citing nurse's statement, P. Ex. 10, at 2, stating that Patient #3 "had been in-serviced by the hospital on the technique to give himself the injection"). Consolidated, however, does not dispute that "Patient #3 injecting himself with the medication without the nurse present *was a violation of the care plan*." ALJ Decision at 11 (emphasis added). There is thus no basis to reverse the ALJ's determination that Consolidated did not implement its care plan for this patient.

We sustain the ALJ's determination that Consolidated was not in compliance with the condition of participation at section 484.18 with respect to Patient #3.

II. Consolidated's arguments about Patient #3 provide no basis to reverse the ALJ's immediate jeopardy determination, which is free of legal error and supported by substantial evidence.

Regarding the determination that Consolidated's noncompliance with section 484.18 with respect to Patient #3 posed immediate jeopardy, Consolidated simply reiterates its rejected claim that its nurse *did* call the hospital physician on July 9 about the missing medication (and failed only to document the call). RR at 6 ("nurse's failure to document the call is serious but not worthy of an IJ citation"). As we have found no basis to reverse the ALJ's finding that Consolidated through its nurse failed to timely contact the physician about the missing medication, this argument provides no basis to disturb the ALJ's finding that Consolidated showed no error in CMS's determination that the condition-level noncompliance was at the immediate jeopardy level.

As discussed above, the ALJ Decision explained the "grave danger" that DVT posed to Patient #3 and concluded that "[a]llowing Patient #3 to be without the prescribed Lovenox for five days following a stay in the hospital without contacting Patient #3's physician could have resulted in serious harm due to blood clots." ALJ Decision at 9, 10, 11-12 (citing information on DVT from the Mayo Clinic Website and the declaration of the nurse surveyor (CMS Ex. 11, at 2)). The SOD also discussed the information from the Mayo Clinic about the dangers of DVT and the threat of resulting blood clots and pulmonary embolism. CMS Ex. 1, at 34. Consolidated did not dispute any of this information or otherwise assert that the lack of the prescribed anticoagulant medication did not pose immediate jeopardy to Patient #3. Consolidated has thus shown no clear error in CMS's immediate jeopardy determination, and no error in the ALJ's determination sustaining the immediate jeopardy finding, which we conclude is supported by substantial evidence and free of legal error. *See* 42 C.F.R. § 498.60(c) ("CMS' determination as to the level of noncompliance of a SNF, NF, or HHA must be upheld unless it is clearly erroneous.").

- III. Consolidated's arguments about Patient #5 and other patients provide no basis to reverse the ALJ's determination that Consolidated was not in compliance with the condition of participation, which is free of legal error and supported by substantial evidence.
 - A. <u>Consolidated did not challenge CMS's noncompliance determination</u> regarding Patient #5 before the ALJ, and permitting it to do so now does not affect the outcome of this case.

The ALJ found that Consolidated "did not dispute CMS's findings" about Patient #5, and concluded that Consolidated "failed to comply with the plan of care for Patient #5 and failed to substantially comply with § 484.18." ALJ Decision at 12. The ALJ found that Consolidated accepted the patient for care but could not show that it provided, or was able to provide, the services the patient required. Consolidated "did not provide a chore worker" as directed in "the patient's July 1, 2015 referral to home health" and "did not notify the physician that, even as of the first survey in August 2015, no chore worker had been provided." *Id.* at 7. Consolidated also failed to follow orders in the care plan for providing oxygen, checking oxygen levels during care, and weighing the patient daily, and that the surveyor observed that "the patient became visibly short of breath" when bathed without oxygen, which "placed Patient #5 in immediate jeopardy." *Id.* at 12.

On appeal, Consolidated now seeks to dispute CMS's and the ALJ's determinations about Patient #5 (and, as we discuss below, other patients about whom Consolidated presented no arguments before the ALJ). The Board *Guidelines*, which were provided to Consolidated with the ALJ Decision, state that the Board "will not consider . . . issues which could have been presented to the ALJ but were not." *Guidelines* at "Completion of the Review Process," ¶ (a); *see Complete Home Care, Inc.*, DAB No. 2525, at 5 (2013) (Board "will not consider issues which could have been presented to the ALJ but were not"); *ACT for Health, Inc.*, DAB No. 1972, at 5 (2005) (Guidelines' prohibition on raising issues not presented to ALJ "mirrors the rule applied in federal appellate courts, which generally refuse to consider issues or arguments raised for the first time on appeal"). CMS argues that the issues relating to Patient #5 and other patients whom Consolidated did not address below "should be considered abandoned by Consolidated" since it "failed to address the deficient care of this patient by the HHA in its brief in the matter before the ALJ." CMS Resp. at 13.

Consolidated explains that in its pre-hearing brief it "decided to address deficiencies relating to only Patient #3 [from] the first survey" because it sought to challenge only the immediate jeopardy determination which, it says, was based on its care of Patient #3. RR at 3. Consolidated alleges that at the exit meeting during the first survey, surveyors told Consolidated to concentrate on Patient #3 in its POC as "that was the IJ level deficiency and could result in the termination," which it says is consistent with the statement in

CMS's pre-hearing brief that "The immediacy of IJ finding, however, was based mostly on the deficient care given to the DVT patient, Patient #3." *Id.* (quoting CMS Br. at 15).

Consolidated thus disputes the ALJ's observation that Consolidated wrongly "seems to believe that the immediate jeopardy relates only to the findings with respect to Patient #3" and the ALJ's finding that "[t]he immediate jeopardy relates to the entire condition-level deficiencies cited with respect to § 484.18 under several tags and with respect to several other patients." ALJ Decision at 6 n.4. CMS responds that "[t]he record supports multiple immediate jeopardy level deficiencies with several patients of Consolidated" and that "[i]ts failure to dispute each and every example in the [SOD] supports the ALJ's decision that the immediate jeopardy level citation is proper." CMS Resp. at 13.

Regardless of whether the record evidence *supports* multiple immediate jeopardy deficiencies involving several patients, the record is not as clear as to whether the immediate jeopardy determination was *based* on findings for multiple patients. The SOD states that "[o]ne condition level deficiency, 418.18 Acceptance of Patients, Plan of Care, and Medical Supervision resulted in a finding of immediate jeopardy (IJ)." CMS Ex. 1, at 1. The SOD's discussion of that deficiency appears to attribute the immediate jeopardy finding to Consolidated's care of Patient #3, stating that "failure to alert the physician created a potential for harm (*resulting in the Immediate Jeopardy cited in this survey*) to the Patient (Record [i.e. Patient] #3), and had the potential to happen to future patients." *Id.* at 32 (emphasis added). CMS's prehearing brief did not address Patient #5 and, as Consolidated notes, stated that "[t]he immediacy of the IJ finding, however, was based mostly on the deficient care given to the DVT patient, Patient #3." CMS Br. at 15.

Ultimately, we need not address whether the immediate jeopardy determination from the first survey was based solely on Consolidated's care of Patient #3, because it would not provide a basis for reducing the penalties imposed.

The \$8,500 per-day CMP in this case is the *minimum* of the "upper range" amounts that "are imposed for a condition-level deficiency that is immediate jeopardy," and is the perday amount CMS imposes "for an isolated incident of noncompliance in violation of established HHA policy." 42 C.F.R. § 488.845(b)(3) (also imposing \$9,000 per day for "a deficiency or deficiencies that are immediate jeopardy and that result in a potential for harm" and "\$10,000 per day for a deficiency or deficiencies that are immediate jeopardy and that result in actual harm"). Thus, finding that Consolidated's condition-level noncompliance was immediate jeopardy with respect to only one patient does not authorize any reduction of the per-day CMP amount, which is already the minimum CMS may impose. (Below we conclude that Consolidated's claim that regulatory factors apply does not warrant any reduction of the per-day CMP amount that is already the minimum amount authorized.) Similarly, limiting the noncompliance findings at issue to only those involving Patient #3 would provide no basis to reverse the termination. "CMS may terminate a HHA's participation in the Medicare program when it determines that the provider is not complying with *one or more* Medicare conditions of participation." *Comprehensive Prof'l Home Visits*, DAB No. 1934, at 13 (2004) (sustaining termination for immediate-jeopardy noncompliance with the condition of participation at section 484.18) (citing Act § 1866(b)(2)(A); and 42 C.F.R. §§ 488.20, 488.24, 488.26, 489.53(a)(1), (3)) (emphasis added). HHA-specific regulations likewise state that CMS may impose sanctions, including termination (and CMPs) on an HHA "on the basis of noncompliance with *one or more* conditions of participation found through a survey" 42 C.F.R. §§ 488.810(b) (emphasis added); 488.820 (listing available sanctions). Thus, Consolidated's immediate-jeopardy noncompliance with the condition of participation at section 484.18 involving Patient #3 by itself authorized CMS to terminate Consolidated's provider agreement.

Finally, Consolidated's arguments about Patient #5 do not warrant reversing the ALJ's noncompliance findings for that patient, as they do not squarely address or allege error in the ALJ's findings. Consolidated alleges that Patient #5 is not blind as the ALJ noted but "only partially blind" which, it argues, "is a very substantial difference." RR at 8. We see nothing in the ALJ's analysis indicating that the degree of the patient's visual impairment was material to the ALJ's finding of noncompliance. Concerning its failure to provide the chore worker services, Consolidated asserts that such services were not ordered by a physician but does not dispute the ALJ's finding that they were required in the referral to home health services and concedes that it did refer the patient to chore worker services. RR at 9.

Consolidated also does not address the ALJ's other noncompliance findings for Patient #5 that support the ALJ's immediate jeopardy determination: that Consolidated failed to follow orders in the care plan for providing oxygen, checking oxygen levels during care, and weighing the patient daily, and that the surveyor observed that "the patient became visibly short of breath" when bathed without oxygen, which "placed Patient #5 in immediate jeopardy." ALJ Decision at 12. Consolidated does not discuss these findings.

We therefore sustain the ALJ's determination that Consolidated did not comply with the condition of participation at section 484.18 and that the noncompliance posed immediate jeopardy.

B. Consolidated's arguments about the other patients the ALJ addressed show no error in the ALJ Decision; Consolidated failed to present these arguments to the ALJ.

The ALJ found Consolidated noncompliant with section 484.18 with respect to Patients #1, #2 and #4 in part because Consolidated in its brief "did not address or specifically dispute" these "issues" or "dispute CMS's findings" from the first survey concerning those patients. ALJ Decision at 7, 8, 12. Consolidated explains that it declined to do so because (as it argues for Patient #5, above) CMS "emphasized the IJ situation" which Consolidated believed did not concern these patients. RR at 10.

On appeal, Consolidated argues that its care of those three patients complied with section 484.18, and submits evidence for Patients #2 and #4, because the ALJ found "that IJ relates to several other patients" in addition to Patient #3. *Id*. (citing the ALJ's finding that the immediate jeopardy "relates to the entire condition-level deficiencies cited with respect to § 484.18... and with respect to several other patients," ALJ Decision at 6 n.4).

Consolidated's rationale for not disputing the initial survey findings for Patients #1, #2, and #4 before the ALJ do not support its attempt to now present arguments (and evidence) about them at this stage of the appeal. Consolidated's rationale – it believed that any immediate jeopardy was limited to Patient #3 – would not permit it to now present arguments about Patients #1, #2 and #4, because the ALJ did not find immediate jeopardy with respect to those patients. Notwithstanding the ALJ's observation in a footnote that the immediate jeopardy relates to findings "with respect to several other patients," the ALJ found immediate jeopardy from the initial survey only with respect to Consolidated's care of Patients #3 and #5, and not Patients #1, #2 or #4. Consolidated stated it intended to challenge only the immediate jeopardy determination.

Finally, as discussed above, the condition-level deficiency findings we sustain regarding Patient #3 are sufficient alone to justify the CMP, which is the minimum authorized for immediate jeopardy, and the termination, which may be imposed for noncompliance with one condition of participation. Thus, reversal of the deficiency finding concerning Patients #1, #2 and #4 would not remove the immediate jeopardy and would not authorize reduction of the CMP or reversal of the termination. Consolidated's arguments concerning those three patients do not warrant ignoring the Board's *Guidelines* dismissing arguments on "issues which could have been presented to the ALJ but were not." *Guidelines* at "Completion of the Review Process," \P (a). We therefore sustain the ALJ's noncompliance findings with respect to Patients #1, #2 and #4.

IV. Consolidated's arguments show no error in the ALJ's determination that Consolidated remained out of compliance with section 484.18 at the immediate-jeopardy level of the revisit survey ending August 28, 2015, which is free of legal error and supported by substantial evidence.

Consolidated disagrees that it did not correct its immediate-jeopardy-level noncompliance with section 484.18 by the time of the revisit survey ending August 28, 2015, authorizing termination. Consolidated argues that "[t]he plan of correction for Patient #3 was adequate to alleviate the Immediate Jeopardy situation and should not have resulted in the termination of the provider agreement." RR at 5. Consolidated specifically disputes that "the nurse's DVT training was not adequate," as the ALJ found in concluding that Consolidated had not abated the noncompliance or the immediate jeopardy, and argues that the "credentials of the DON and the key nurse" who provided the training "are included in [its] exhibits 24 and 25" and "have never been questioned in the past." RR at 6 (citing P. Ex. 24 ("key nurse" job application), and P. Ex. 25 (DON credentials)).

The surveyor's findings about the inadequacy of the DVT training that the ALJ Decision quoted do not concern the background credentials of the DON or the "key nurse," and instead reflect the surveyor's review of the training materials, and interviews with staff who had taken the training "to assess their comprehension of DVT," which found that "their answers were usually incorrect, not consistent, and below the standard for competent patient care." CMS Ex. 12, at 2. The nurse surveyor stated that this "lack of knowledge of the risks of and care for patients with DVT went all the way up to the Director of Nursing who did not seem to understand the difference between thrombosis and phlebitis." *Id.* at 2-3. Consolidated has not addressed this testimony or the ALJ's evaluation of the evidence of the inadequacy of the DVT training that Consolidated obliged itself to provide to its staff.

Moreover, the inadequacy of the DVT training was not the only reason the ALJ concluded Consolidated failed to timely correct its noncompliance with section 484.18 and "remained out of compliance" at the revisit survey. The ALJ also determined that Consolidated had failed to implement the commitments in its POC that the QI nurse would conduct "reviews of patient status, services provided, and medications and discussion of interim orders written during the week"; would "review all active charts and discharges 'with the newly updated QI tool[]"; and would "review all discipline notes and notify staff members of missing paperwork" and that staff would submit corrections "immediately" to the QI nurse. ALJ Decision at 13 (citing CMS Ex. 7). The ALJ found that during the revisit survey the DON provided "only three chart audits: one completed by the DON and two completed by a staff nurse who was helping out in the evening." *Id.* The POC also promised that nurses would "use a care plan book to

develop a personalized care plan on each patient" but Consolidated had not done so as of the revisit. *Id.* (citing CMS Ex. 2, at 10-11 and CMS Ex. 7, at 2).

Consolidated has not disputed the ALJ's findings or alleged that it did in fact successfully and timely implement these measures from its POC, contrary to what the revisit survey found. Consolidated has thus not shown that it took the measures that it listed in its POC as necessary to achieve substantial compliance with section 484.18.

The ALJ also found Consolidated did not dispute that during the revisit survey, surveyors observed Consolidated's nurses failing to implement standard infection control precautions while caring for Patients # 1 and #2, as their care plans required, and that Consolidated did not dispute that. ALJ Decision at 7-8, 13. Consolidated disputes the ALJ's determination for Patient #2, arguing that it did address the findings in its brief and that it violated no procedures in caring for the patient's wound. RR at 12; P. Br. at 13. Consolidated cites its Exhibit 38, comprising a progress note from a wound clinic, written communications between the wound clinic and Consolidated's DON, and two photographs of the bandaged wound. These materials indicate that the wound clinic examined Patient #2's wound on September 1, 2015 and found it dressed appropriately as a physician had ordered. P. Ex. 38. Consolidated also cites a statement from the patient stating that the Consolidated nurse who dressed his wound did not "move" the dressing, as the patient says was reported by two nurses, presumably surveyors.

These materials are of limited probative value as they relate to the appearance of the dressing on the wound, while the surveyor found noncompliance based on the unsanitary conduct of the nurse while dressing the wound. The surveyor found that the nurse "failed to remove dirty exam gloves and use hand sanitizer prior to handling patient's admission folder and paperwork" and, after removing the "dirty exam gloves" did not use hand sanitizer before placing "assessment equipment back into [the] clean nursing bag" and "failed to clean the equipment prior to placing back in to [the] nursing bag." CMS Ex. 2, at 21. That the wound was observed to have a proper dressing and was fortuitously not infected several days later does not contradict the surveyor's observations or verify that the nurse followed appropriate infection control precautions when dressing the wound. The patient's very general statement also says nothing about whether Consolidated's nurse implemented proper infection control precautions during care. Consolidated has thus shown no basis to question the ALJ's decision to credit the surveyor's observations as recorded in the SOD. See Life Care Ctr. of Bardstown, DAB No. 2479, at 19 (2012) ("[T]he SOD itself constitutes prima facie evidence of the facts asserted in it."), aff'd, Life Care Ctr. of Bardstown v. Sec'y of U.S. Dep't of Health & Human Servs., 535 F. App'x 468 (6th Cir. 2013).

We thus sustain the ALJ's determination that Consolidated remained out of compliance with the condition of participation at section 484.18 and that its noncompliance was immediate jeopardy.

V. There is no basis to reduce the per-day CMP that CMS imposed and the ALJ sustained, which is the minimum CMS imposes for a condition-level deficiency that constitutes immediate jeopardy.

Consolidated does not specifically dispute the ALJ's conclusion that the \$8,500 per-day CMP is "authorized under the applicable regulations" (FFCL #2, ALJ Decision at 14), but argues that the amount imposed "does not seem to be commensurate with other situations from case review especially considering this was a one IJ situation" and that the "factors to be considered . . . do not seem to have been considered." RR at 15. Consolidated cites two Board decisions in nursing home appeals from 2004 and one from 1999 as showing more lenient treatment, and argues that the regulatory factors and equitable considerations warrant a lower or no CMP.

These arguments provide no basis to reduce the CMP because we conclude that the ALJ and the Board are not authorized to reduce a per-day CMP imposed on an HHA that is already set at the minimum amount that the regulations authorize CMS to impose for the noncompliance at issue.

In appeals by nursing facilities of CMPs imposed under subpart F of Part 488 (42 C.F.R. §§ 488.400-456), which, like the HHA regulations, sets ranges of per-day CMP depending on whether there is immediate jeopardy (§ 488.438(a)), the Board has held that where "the per-day CMP amounts that CMS imposed . . . were the minimum amounts that CMS was permitted to impose under section 488.438(a)(1) . . . they are reasonable as a matter of law, regardless of [the facility's] financial condition, history of noncompliance, or other factors." *Magnolia Estates Skilled Care*, DAB No. 2228, at 28 (2009) (citing *Sheridan Health Care Ctr.*, DAB No. 2178, at 44 (2008); *Premier Living & Rehab Ctr.*, DAB No. 2146, at 22 (2008); and *Century Care of Crystal Coast*, DAB No. 2076, at 26 (2007)). Thus, "[o]nce we determine that a legal basis existed for CMS to impose a CMP within one of the regulatory penalty ranges, we have no authority to reduce the CMP amount below the minimum amount specified by the applicable penalty range." *Id.* at 28-29.

The Board based this conclusion on language in the preamble to the final rule limiting review of CMPs that CMS imposes on nursing facilities, at 42 C.F.R. § 488.438(e). That regulation states that "[w]hen an administrative law judge or State hearing officer (or higher administrative review authority) finds that the basis for imposing a civil monetary penalty exists, as specified in § 488.430, the [ALJ or other reviewer] may not— (1) Set a penalty of zero or reduce a penalty to zero; . . . [r]eview the exercise of discretion by CMS or the State to impose" a CMP; or "[c]onsider any factors in reviewing the amount of the penalty other than those specified" in the regulations. The preamble language for this provision that the Board cited states that "when the administrative law judge or State hearing officer (or higher administrative review authority) finds noncompliance supporting the imposition of the civil money penalty, he or she must remedy it with some

amount of penalty *consistent with the ranges of penalty amounts established* in § 488.438." 59 Fed. Reg. 56,116, 56,206 (Nov. 10, 1994) (emphasis added); *Magnolia Estates Skilled Care* at 29; *Gilman Care Ctr.* DAB No. 2357, at 6 (2010) (both quoting preamble language). Based on this language, the Board concluded that it and ALJs may not apply regulatory factors to reduce a CMP that is already set at the minimum of the range that CMS may impose. *Magnolia Estates Skilled Care* at 29 and cases cited therein.

Section 488.485(h) of the HHA CMP regulations, which limits review of CMP amounts in HHA appeals, is substantively identical to section 488.438(e). The preamble to the rule implementing section 488.485(h) is substantively identical to the preamble language that the Board relied on in concluding that it may not reduce a CMP below the minimum amount specified in the regulation. The preamble to the HHA CMP rule states, "[W]hen the administrative law judge or state hearing officer (or higher administrative review authority) finds noncompliance supporting the imposition of the CMP, he or she must retain some amount of penalty consistent with the ranges of penalty amounts established in § 488.845(b)." 79 Fed. Reg. 66,032, 66,108 (Nov. 6, 2014) (emphasis added). The preamble contains further language supporting application of the restriction we recognized in *Magnolia* and other cases. *Id.* at 66,108-09 ("While an ALJ may review the underlying findings that support CMS's determination to impose a CMP and whether or not the imposed amount falls within the regulatory range, elimination of any CMP is not within the scope of the appeal process." (emphasis added)). Thus, based on our holding in Magnolia and other cases, we conclude that Consolidated's arguments provide no basis to reduce the per-day CMP that CMS imposed, which is the minimum amount that the regulations impose for, as here, condition-level noncompliance that poses immediate jeopardy.

Finally, we note that Consolidated has not met its burden of establishing the presence of regulatory factors that could reduce the per-day CMP amount. In nursing facility cases, which involve CMP regulations similar to the HHA CMP regulations, the Board has consistently held that "the burden is not on CMS to present evidence bearing on each regulatory factor, but on the [facility] to demonstrate, through argument and the submission of evidence addressing the regulatory factors, that a reduction is necessary to make the CMP amount reasonable." *Crawford Healthcare & Rehab.*, DAB No. 2738, at 19 (2016) (citing *Oaks of Mid City Nursing & Rehab. Ctr.*, DAB No. 2375, at 26-27 (2011)); *see also Brenham Nursing & Rehab Ctr.*, DAB No. 2619, at 18 (2015) (holding that it was the facility's burden to introduce evidence or argument regarding the regulatory factors), *aff'd*, *Brenham Nursing & Rehab Ctr. v. U.S. Dep't of Health & Human Servs.*, 637 F. App'x 820 (5th Cir. 2016). Consolidated below made general assertions about its size and financial condition but did not cite or provide any exhibits in evidence to support its claims.

We thus conclude that there is no basis to reduce the per-day CMPs that CMS imposed, which are reasonable.

VI. CMS was authorized to terminate Consolidated's participation in the Medicare program.

As we noted previously, the HHA regulations authorize CMS to terminate a HHA's participation in the Medicare program when it determines that the provider is not complying with one or more Medicare conditions of participation. 42 C.F.R. §§ 488.810(b); 488.820; *see* Act § 1891(e), (f). We sustained above the ALJ's findings that Consolidated was not in compliance with the condition of participation at section 484.18 requiring HHAs to meet patients' needs and follow the plan of care set by the physician, that the noncompliance was immediate jeopardy, and that Consolidated failed to correct the noncompliance or the immediate jeopardy as verified by the revisit survey. We thus conclude that CMS was authorized to terminate Consolidated's Medicare participation.

Conclusion

For the reasons explained above, we affirm the ALJ Decision upholding the remedies imposed by CMS.

/s/ Constance B. Tobias

/s/

Susan S. Yim

/s/

Christopher S. Randolph Presiding Board Member