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No. 19-3755

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

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GOLDEN LIVING CENTER – MOUNTAIN VIEW, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES Respondents.	ON PETITION FOR REVIEW FROM THE UNITED STATES DEPARTENT OF HEALTH AND HUMAN SERVICES

BEFORE: BOGGS, CLAY, and GIBBONS, Circuit Judges.

JULIA SMITH GIBBONS, Circuit Judge. Petitioner Golden Living Center – Mountain View ("Mountain View") is a Tennessee skilled nursing facility ("SNF") that participates in the federal Medicare and Medicaid programs. As a participant in these programs, Mountain View is required to be in substantial compliance with federal requirements for such facilities. Following an inspection of the facility in April 2014, when inspectors learned of an increase in patient falls in the Alzheimer's Care Unit ("ACU"), Centers for Medicare and Medicaid Services ("CMS") determined that Mountain View was not in substantial compliance with several regulatory requirements. CMS imposed a civil monetary penalty ("CMP") in the amount of $621,250. An administrative law judge ("ALJ") and the Departmental Appeals Board of the Department of Health and Human Services ("DAB") both affirmed the administratively imposed penalties.

Mountain View appeals the DAB decision, arguing that the imposition of the CMP was arbitrary and capricious because it did not have notice from the statute or regulations that CMS

would fine it for not considering adding additional staff. While it seems likely that CMS may have gathered sufficient evidence to find that Mountain View was not in compliance with the regulations due to the increased falls that residents experienced without adequate intervention from the facility, the DAB's decision rested exclusively on Mountain View's failure to consider increasing its staffing. Because the regulations that CMS cited did not provide notice to Mountain View that it must specifically consider increased staffing and review each patient's care plan after every fall, we agree that CMS's decision was arbitrary and capricious. We reverse and remand to the DAB for proceedings consistent with this opinion.

I.

A.

Mountain View is a skilled nursing facility in Tennessee that participates in the federal Medicare and Medicaid programs. *See* 42 C.F.R. § 488.3 (as effective 2014). As a skilled nursing facility, it is required to comply with 42 U.S.C. § 1395i-3 and 42 C.F.R. § 483, and it is surveyed periodically to assure compliance with federal regulations, *see id.* §§ 488.7; 488.20; 488.308.

A state agency, with CMS authorization, surveys facilities and records instances of noncompliance known as deficiencies. *See id.* § 488.404(b). The surveyors note deficiencies and assign scope and severity levels, indicated by an alphabetic character A through L, ranging from the lowest, "no actual harm but has the potential for minimum harm," to the highest, noncompliance that causes "immediate jeopardy to resident health or safety." (CA6 R. 16, Pet'r Am. App., ALJ Am. Decision, PageID 34 n.4.) Immediate jeopardy occurs when noncompliance "has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301 (as effective 2014).

If CMS finds that a facility's noncompliance has placed residents in immediate jeopardy, CMS can impose a CMP ranging from $3,050 to $10,000 per day. *Id.* § 488.438(a)(1)(i). For deficiencies of lesser severity that caused harm or have the potential for more than minimal harm, CMS may impose a CMP ranging from $50 to $3,000 per day. *Id.* § 488.438(a)(1)(ii).

CMS mails a notice of its determination to the facility under 42 C.F.R. § 498.20(a)(1), and a nursing facility dissatisfied with an initial determination is entitled to a hearing before an ALJ under § 498.5(b) and § 488.408(g) if it files a request within 60 days of the determination. *Id.* §§ 498.40(a)(2), 488.330(e)(3). The request for a hearing must specify the findings of fact and legal conclusions with which the provider disagrees and the basis for those contentions. *Id.* § 498.40(b). An ALJ, under § 488.438(e), may not reduce or set a penalty to zero or review CMS's exercise of discretion in selecting a penalty if the ALJ finds there is a basis for imposing the penalty. *Id.* § 498.60(c).

An ALJ reviews *de novo* the legal and factual basis for the alleged regulatory noncompliance. *Life Care Ctr. of Bardstown v. Sec'y U.S. Dep't of Health & Human Servs.*, 2012 WL 5290709, No. 2479, *7 n.4 (DAB 2012) ("The ALJ review is de novo, and the 'issue before the ALJ is "whether the evidence as it is developed before the ALJ" supports the finding of noncompliance, "not . . . how CMS evaluated the evidence as it stood at whatever point CMS made its assessment."'" (quoting *Sunbridge Care & Rehabilitation for Pembroke*, No. 2170 (DAB 2008))) *aff'd* 535 F. App'x 468 (6th Cir. 2013). Additionally, "CMS'[s] determination as to the level of noncompliance of [a skilled nursing facility] [i.e. immediate jeopardy] . . . must be upheld unless it is clearly erroneous." *Id.* at *27.

A facility dissatisfied with the hearing decision by the ALJ may request review by the DAB and may seek judicial review of the DAB's decision by filing a request for review within 60 days

of the ALJ decision. 42 C.F.R. §§ 498.5(c); 498.82. The request for review "must specify the issues, the findings of fact or conclusions of law with which the party disagrees, and the basis for contending that the findings and conclusions are incorrect." *Id.* § 498.82(b). Review is conducted by a panel of at least two members of the DAB, and the DAB may admit into the record additional evidence it believes relevant and material. *Id.* § 498.86(a). The DAB's decision must be "based upon the evidence in the hearing record and any further evidence that the [DAB] receive[d] during its review" and must be "in writing and contain[] separate numbered findings of fact and conclusions of law." *Id.* § 498.88(f). The DAB reviews factual issues to determine if the "ALJ decision is supported by substantial evidence in the record as a whole" and legal issues to determine if the "ALJ decision is erroneous." *Avon Nursing Home*, 2017 WL 7734852, No. 2830, *7 (DAB 2017). A party dissatisfied with the DAB's determination is then entitled to seek judicial review within 60 days. 42 C.F.R. § 498.5.

B.

The factual background of this case is nearly undisputed. From March 31, 2014 through April 11, 2014, surveyors from the Tennessee State Survey Agency ("SSA"), pursuant to an agreement with CMS, conducted an annual recertification and extended survey of operations at Mountain View. *See id.* § 488.10 (as effective in 2014). The surveyors uncovered and observed numerous instances where Mountain View was not in substantial compliance with federal regulations. Specifically, the surveyors determined that Mountain View's noncompliance with seven regulations (noted under six F-Tags) posed immediate jeopardy. These violations included: "42 C.F.R. §§ 483.20(d)(3) and 483.10(k)(2) ["F280"] (care plans); 483.25(h) ["F323"] (accident hazards); 483.30(a) ["F353"] (adequate staffing); 483.75 ["F490"] (administration); 483.75(i) ["F501"] (medical director); and 483.75(o)(1) ["F520"] (Quality Assurance

Committee)." (AR 278, Vol. 1., Joint Stipulations.)[1] The surveyors also noted other deficiencies at lower severity levels, but these deficiencies were not challenged by Mountain View.

The basis for all of the deficiencies posing immediate jeopardy was numerous unwitnessed falls, over forty during a period of four months, by five residents of Mountain View's Alzheimer's Care Unit ("ACU"). Mountain View has a specially licensed ACU that houses between thirty to thirty-five residents diagnosed with Alzheimer's disease or other cognitive disorders who are "able to pivot during transfer and be ambulatory, but may use a walker, wheelchair, or other assistive devices." (CA6 R. 15, Pet'r Am. App., ALJ Decision, PageID 40.) Each resident was determined to be at a high risk for falls due to various mental and physical ailments. These falls caused injuries, requiring emergency medical evaluation or first aid. The surveyors concluded that the repeated, unwitnessed falls placed these five residents in immediate jeopardy.

CMS notified Mountain View of the deficiencies on April 23, 2014. CMS imposed an initial civil monetary penalty ("CMP") on Mountain View in the amount of $5,800 per day, effective January 13, 2014, until the facility achieved substantial compliance.

Subsequently, on May 1, 2014, the Tennessee SSA conducted a revisit survey to determine whether Mountain View had achieved substantial compliance. The surveyors concluded that Mountain View was still not in substantial compliance, but also noted these deficiencies no longer posed immediate jeopardy to its residents. CMS modified the CMP to accrue at a rate of $150 per day, effective April 29, 2014, until CMS determined the facility was in substantial compliance. Tennessee SSA conducted a second revisit survey on June 11, 2014 and found that Mountain View had returned to substantial compliance. CMS imposed a total CMP of $621,250; CMS first applied

[1] Both CMS and the ALJ incorrectly cited the regulatory violation as § 483.20(d)(3) instead of § 483.10(d)(3), and § 483.10(k)(2) instead of § 483.20(k)(2). The DAB noted and corrected this error.

a penalty of $5,800 per day for a total of 106 days then modified the penalty to $150 per day for a period of 43 days.

Mountain View appealed the penalty. Under the *Hillman* standard applied by the ALJ and DAB, the agency must first provide evidence sufficient to establish a *prima facie* case of the regulatory violation. *Hillman Rehabilitation Ctr. v. Health Care Financing Admin.*, 1997 WL 123708, No. 1611 (DAB 1997). Once the agency has met its burden, then the burden of persuasion shifts to the facility to "prove by a preponderance of the evidence on the record as a whole that it is in substantial compliance with the relevant statutory and regulatory provisions." *Id.* at *4–5. The DAB continues to apply this burden-shifting framework in analyzing the penalty against Mountain View. (CA6 R. 15, Pet'r Am. App., DAB Decision, PageID 14.)

The ALJ concluded that "CMS ha[d] made a *prima facie* showing of noncompliance under Tags F280, F323, F353, F490, F501, and F520." (CA6 R. 15, Pet'r Am. App., ALJ Decision, PageID 14, 74.) The ALJ specifically relied on the undisputed evidence of the residents' falls, that Mountain View's staffing for direct care fell below the level required for an ACU by Tennessee regulation establishing the presumptive standard of practice, and the surveyors' perceptions that "staff on duty were having difficulty delivering the level of care and services residents required during the period of the survey." (*Id.* at 76.)

Rather than holding that CMS had sufficient evidence from which to infer noncompliance with the relevant regulations, the ALJ found that Mountain View was noncompliant with F323 ("Accidents") purely because it failed to consider adding additional staffing. The ALJ in turn relied on the violation of F323 to affirm CMS findings of violations under F323, F490, F501 and F520. The ALJ reasoned that "[i]ncreasing staff is an obvious potential intervention to address increased resident needs, something the [Quality Assurance] committee and management failed to

consider." (CA6 R. 15, Pet'r Am. App., ALJ Decision, PageID 83.) The ALJ continued: "[I]t should have been obvious to the QA committee and management that the staffing ratio on the ACU may have required adjustment to provide additional supervision and assistance to the five residents experiencing an increase in falls." (*Id.*) The ALJ rejected Mountain View's defense that the falls were unavoidable because Mountain View "cannot establish its defense by a preponderance of the evidence when it cannot show that increased staffing or an adjustment of staffing on the ACU was not an appropriate and effective intervention." (*Id.*)

The DAB affirmed the ALJ's decision. The DAB summarily "conclude[d] without further discussion that substantial evidence supports the ALJ decision on all material factual issues" because Mountain View "d[id] not specifically argue that the ALJ Decision is not supported by substantial evidence," rather it alleged legal errors by the ALJ. (CA6 R. 15, Pet'r Am. App., DAB Decision, PageID 16–17.) Mountain View timely appealed.

II.

Our review of DAB decisions is highly deferential. *Woodstock Care Ctr. v. Thompson*, 363 F.3d 583, 588 (6th Cir. 2003). With respect to questions of fact, "[t]he findings of the Secretary . . . if supported by substantial evidence on the record considered as a whole, shall be conclusive." *Id.* (quoting 42 U.S.C. § 1320a-7a). "When conducting substantial evidence review, this Court examines the record as a whole and takes into account whatever in the record fairly detracts from the weight of the evidence below." *Claiborne-Hughes Health Ctr. v. Sebelius*, 609 F.3d 839, 843 (6th Cir. 2010) (quoting *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 488 (1951)). The court "do[es] not consider the case *de novo*, nor resolve conflicts in the evidence, nor decide questions of credibility." *MeadowWood Nursing Home v. U.S. Dep't of Health*

& Human Servs., 364 F.3d 786, 788 (6th Cir. 2004) (quoting *Myers v. Sec'y of Health & Human Servs.*, 893 F.2d 840, 842 (6th Cir. 1990)).

As to questions of law, an agency's interpretation of statutes "[is] given controlling weight unless [it is] arbitrary, capricious, or manifestly contrary to the statute." *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council*, 467 U.S. 837, 843 (1984). If a statute's meaning is plain, courts "must give effect to the unambiguously expressed intent of Congress." *Chevron, U.S.A., Inc.*, 467 U.S. at 843. Under *Chevron*, a court will defer to an agency's reasonable interpretation when "Congress has explicitly left a gap for the agency to fill" or if the statute is ambiguous after application of "traditional tools of statutory construction." *See Chevron*, 467 U.S. at 843 n.9, 843–44, 865; *see also Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019).

Under *Auer v. Robbins*, 519 U.S. 452 (1997), deference is also sometimes due to an agency's interpretation of a genuinely ambiguous *regulation* (formerly known as *Seminole Rock* deference). *Kisor*, 139 S. Ct. at 2414. Such interpretations are not substantive rules, and thus do not create or carry the force of law. *Dismas Charities, Inc. v. Dep't of Justice*, 401 F.3d 666 (6th Cir. 2005) (quoting *First Nat'l Bank v. Sanders*, 946 F.2d 1185, 1188–89 (6th Cir. 1991)); *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1811 (2019) ("'[I]nterpretive rules' are those that merely 'advise the public of the agency's construction of the statutes and rules which it administers.'" (quoting *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 97 (2015))); *Nat'l Min. Ass'n v. McCarthy*, 758 F.3d 243, 252 (D.C. Cir. 2014) ("An agency action that merely explains how the agency will enforce a statute or regulation—in other words, how it will exercise its broad enforcement discretion or permitting discretion under some extant statute or rule—is a general statement of policy.").

In reviewing an agency's interpretation of a regulation, a court must first "resort[] to all the standard tools of interpretation" to determine if the regulation is genuinely ambiguous. *Kisor*, 139 S.Ct. at 2414. Further, not all interpretations are entitled to deference; no deference is warranted for an agency interpretation that "does not reflect an agency's authoritative, expertise-based, 'fair[, or] considered judgment.'" *Id.* (alteration in original) (quoting *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 155 (2012)). An agency's interpretation must be reasonable, meaning "it must come within the zone of ambiguity the court has identified after employing all its interpretive tools." *Id.* at 2416. The agency's interpretation must also be "the agency's 'authoritative' or 'official position,' rather than . . . [an] ad hoc statement not reflecting agency views," "implicate its substantive expertise," and "must reflect 'fair and considered judgment.'" *Id.* at 2416–17.

An ad hoc interpretation arising in the context of an enforcement proceeding receives no deference under *Auer*, as it is not an official agency position, and would "unfairly surprise the sanctioned party and 'seriously undermine the principle that agencies should provide regulated parties fair warning of the conduct [a regulation] prohibits or requires.'" *Elgin Nursing & Rehabilitation Ctr. v. U.S. Dep't of Health & Human Services*, 718 F.3d 488, 493–94 (5th Cir. 2013) (quoting *SmithKline Beecham Corp.*, 567 U.S. at 156) (quotation marks omitted)).The Supreme Court has, therefore, counseled reticence in applying agency interpretations that give rise to "unfair surprise." *Id.* at 158 (refusing to rely on an agency interpretation of a regulation advanced for the first time in an *amicus brief* filed the same year the litigation commenced); *see also Kisor*, 139 S. Ct. at 2421 ("[D]eference turns on whether an agency's interpretation creates unfair surprise or upsets reliance interests.").

Our review of the CMP is also governed by the Administrative Procedure Act ("APA"). An agency's decision is arbitrary and capricious if "the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Taylor v. Principi*, 92 F. App'x 274, 276–77 (6th Cir. 2004) (quoting *Henry Ford Health Sys. v. Shalala*, 233 F.3d 907, 911 (6th Cir. 2000)). "At base, arbitrary and capricious review functions to 'ensur[e] that agencies have engaged in reasoned decisionmaking.'" *Atrium Med. Ctr. v. U.S. Dep't of Health & Human Servs.*, 766 F.3d 560, 567 (6th Cir. 2014) (quoting *Judulang v. Holder*, 565 U.S. 42, 53 (2011)).

If an agency interpretation would not provide fair notice to the regulated parties, then the courts should not defer to it, and instead must review the agency interpretation of the regulation to determine whether the agency's action is "arbitrary and capricious" or "not in accordance with law." 5 U.S.C. § 706(2); *Kisor*, 139 S.Ct. at 2414 ("*Auer* deference is not the answer to every question of interpreting an agency's rules. Far from it. As we explain in this section, the possibility of deference can arise only if a regulation is genuinely ambiguous").

III.

Mountain View claims that the facility was in substantial compliance with the applicable regulations and that the DAB's decision was arbitrary and capricious because it failed to provide a reasoned basis for determining Mountain View's obligation to consider additional staffing under each of the cited regulatory violations. Because neither the ALJ nor the DAB offered explanations supporting the conclusion that the facility was on notice that it must consider additional staffing under each of the alleged regulatory violations, we remand to the DAB for further proceedings.

Because the ALJ and DAB narrowly rested their decision on the failure to consider staffing, a basis on which Mountain View had no notice anywhere in the regulations, we do not address the broader issue of Mountain View's compliance.

The question before this court is not whether, based on the totality of the evidence, the ALJ or DAB could properly have found that Mountain View was not in compliance with the regulations. Rather, the question is whether CMS had properly put Mountain View on notice that failure to consider adding additional staffing in the face of unwitnessed falls would constitute a violation. We hold that it did not.

A.

Congress created the Medicaid and Medicare programs and delegated authority to the Secretary of HHS to promulgate regulations necessary to carry out the administration of these programs. *See* 42 U.S.C. § 1395hh. Within HHS, CMS was created to manage the federal Medicare and Medicaid programs. *Centers for Medicare & Medicaid Services*, 66 Fed. Reg. 35437-03 (July 5, 2001). The Administrator of CMS has delegated authority to promulgate regulations to implement the various federal programs that CMS controls. *Id.* Pursuant to this authority, it promulgates both substantive rules and interpretive rules.

CMS's substantive rules governing skilled nursing facilities, like Mountain View, have the force of law because they conform with the procedural requirements of notice and comment and "affect[] individual rights and obligations." *Chrysler Corp. v. Brown*, 441 U.S. 281 (1979) (quoting *Morton v. Ruiz*, 415 U.S. 199, 235 (1974)).

On the other hand, CMS has issued interpretative rules in agency manuals, such as the State Operations Manual ("SOM") at issue here, interpreting these regulations. *Clarian Health West,*

LLC v. Hargan, 878 F.3d 346, 380 (D.C. Cir. 2017) (CMS Manual "instructions are a general statement of policy").

Further, CMS interprets its own regulations ad hoc, for example, through litigation positions. *Kisor v. Wilkie*, 139 S. Ct. 2400, 2417 (2019). Such agency guidance does not require notice and comment, and does "*not* have the force of law." *Id.;* 5 U.S.C. § 553(b)(3)(A). As explained above, deference is due to an agency's interpretation of a genuinely ambiguous regulation, *Kisor*, 139 S. Ct. at 2414, but an interpretive rule, such as the one in question, "receives no deference under *Auer*." *Gonzales*, 546 U.S. at 258. Additionally, "[w]hen an agency promulgates regulations it is… bound by those regulations. It may not attempt to subvert the rule-making process through interpretations that find no support in the regulation's language." *A.D. Trasport. Express, Inc. v. United States*, 290 F.3d 761, 766 (6th Cir. 2002). Relying on these precedents, other circuits have declined to defer to CMS's interpretation of the SOM in an enforcement action precisely because doing so deprived the nursing home "of fair notice of the wrong to be avoided." *Elgin Nursing & Rehabilitation Ctr. v. Dep't of Health & Human Servs.*, 718 F.3d 488, 493–94 (5th Cir. 2013) (discussing *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142 (2012)). Nowhere in the regulations does CMS put nursing homes on notice that consideration of additional staffing will be dispositive. Instead, CMS argues that it is "obvious." Because this interpretation of this regulation arose through enforcement, rather than notice and comment, we do not give it the deference that we give substantive rules that went through the notice and comment process. *Kisor,* 139 S.Ct.at 2418; *Auer v. Robbins*, 519 U.S. 452 (1997). After determining whether deference is appropriate, we determine whether the agency's application of the regulation to Mountain View was arbitrary and capricious.

B.

CMS found that Mountain View was not in substantial compliance with seven regulations at a level causing immediate jeopardy to its residents. These violations included: "42 C.F.R. §§ 483.20(d)(3) and 483.10(k)(2) ["F280"] (care plans); 483.25(h) ["F323"] (accident hazards); 483.30(a) ["F353"] (adequate staffing); 483.75 ["F490"] (administration); 483.75(i) ["F501"] (medical director); and 483.75(o)(1) ["F520"] (Quality Assurance Committee)." (AR 278, Vol. 1, Joint Stipulations.) We review each regulation below.

On appeal, Mountain View argues that it lacked fair notice of the regulations' requirement that a skilled nursing facility consider additional staffing in response to an increase in falls and revise a patient's care plan after every fall. CMS argues that the requirement represents a common-sense understanding of the regulations. We agree with Mountain View. The regulations did not provide Mountain View fair notice that it was required to consider additional staffing in response to an increase in falls. As an ad hoc interpretation of its own regulations, arising solely through enforcement, this interpretation is owed no deference, and we find that it was arbitrary and capricious.

Additionally, substantial evidence does not support the ALJ's and DAB's conclusions that Mountain View was not reviewing resident care plans after falls, that it did not have adequate nursing staff, that the quality assurance committee was not properly constituted, and that Mountain View's Medical Director was failing to ensure Mountain View's policies and procedures were being implemented. Accordingly, we reverse the DAB's decision in full.

1. F280: Violations of 42 C.F.R. §§ 483.10(d)(3) and 483.20(k)(2)

Section 483.10(d)(3), as effective in 2014, provides that a resident has the right to, "[u]nless adjudged incompetent or otherwise found to be incapacitated under the laws of the State,

participate in planning care and treatment or changes in care and treatment." In 2014, § 483.20(k)(2), regarding comprehensive care plans, provided: "A comprehensive care plan must be—(i) Developed within 7 days after completion of the comprehensive assessment; (ii) Prepared by an interdisciplinary team, that includes the attending physician, a registered nurse with responsibility for the resident, and other appropriate staff in disciplines as determined by the resident's needs, and, to the extent practicable, the participation of the resident, the resident's family or the resident's legal representative; and (iii) Periodically reviewed and revised by a team of qualified persons after each assessment."

"Periodic" leaves some ambiguity as to how frequently a facility must review and revise a resident's care plan. The dictionary provides that "periodic" means "recurring at regular intervals" or "intermittently." *Periodic*, Oxford English Dictionary (3d ed. 2005). Those definitions resolve some ambiguity—they clarify review and revision of care plans occurs "regularly," rather than in response to certain events—they leave other ambiguities—namely, how much time should pass between each review and revision.

CMS's statement of deficiencies provides that Mountain View was not in substantial compliance with section 42 C.F.R. §§ 483.10(d)(3) and 483.20(k)(2) because "the facility failed to follow policy to revise care plans after every fall for appropriate interventions to prevent further falls" for the five residents in the ACU. (CA6 R. 18, Resp't App., Statement of Deficiencies, PageID 71.) "The facility's failure to review and revise residents' care plans, develop, and implement appropriate interventions to prevent falls placed [the residents] in [i]mmediate [j]eopardy." (*Id.*) As evidence of this noncompliance, CMS cited each resident's medical records documenting the falls and noted whether additional interventions were implemented or added to a resident's care plan after each fall.

The ALJ, reviewing the Statement of Deficiencies and the surveyors' testimony, determined that one surveyor found Mountain View "deficient because residents fell and no new intervention was added to their care plan," and similarly, the other surveyor concluded that "the fall had to be assessed and a new intervention added to ensure that the resident does not fall again." (CA6 R. 15, Pet'r Am. App., ALJ Decision, PageID 63–64.)

The ALJ, interpreting the regulation, found that "483.20(k) does not impose a requirement and the parties have identified no standard of practice that requires that a new intervention be implemented or that interventions be changed due to the occurrence of an accident[, and] conclude[d] that failure to implement a new intervention following a fall, standing alone, [wa]s not a sufficient basis to find noncompliance." (*Id.* at 78–79.) Despite determining that under the regulation a provider was not required to change an intervention or implement a new intervention after every fall, and finding that "[t]he evidence summarized above shows that the residents' IDTs were actively involved in assessing, implementing interventions, and evaluating the effectiveness of those interventions," the ALJ concluded that Mountain View was not substantially compliant with these regulations.[2] (*Id.*) This determination, as upheld by the DAB, was not supported by substantial evidence.

The regulation is clear on its face that an IDT is required to develop a comprehensive care plan and "periodically review and revise" it. § 483.20(k)(2). Mountain View reviewed each resident's care plan after a fall and modified the care plan to add or change resident interventions as needed. There was "no dispute about the material facts establishing and surrounding each fall." (CA6 R. 15, Pet'r Am. App., DAB Decision, PageID 13.) The only question for the ALJ and DAB

[2] Notably, the ALJ also affirmed the CMS's determination of noncompliance with §§ 483.20(d)(3) and 483.10(k)(2), which are not the correct regulatory provisions. Although the ALJ cited the correct regulatory sections when describing the requirements a provider must adhere to, the ALJ did not correctly include these regulations in his conclusions of law.

to resolve was whether, as presented by the undisputed facts, CMS's interpretation of the regulation that Mountain View was required to add or change its interventions after each instance of a resident fall in order to be in substantial compliance was consistent with the regulations. CMS's interpretation, as the ALJ pointed out, is inconsistent with the regulations requiring periodic review. Moreover, Mountain View was not on notice that CMS interpreted the regulations to require it to amend patients' care plans after every fall to be in substantial compliance with the regulation. The DAB erred in concluding that CMS met its burden to show that Mountain View violated these regulations.

2. F323: Violation of 42 C.F.R. § 483.25(h)

Section 483.25(h), as in effect in 2014, requires the facility to "ensure that — (1) [t]he resident environment remains as free of accident hazards as is possible; and (2) [e]ach resident receives adequate supervision and assistance devices to prevent accidents." The regulation is ambiguous on its face as to what level of care is required to achieve "adequate supervision." *See Ashbury Ctr. v. U.S. Dep't of Health & Human Servs.*, 77 F. App'x 853, 857 (6th Cir. 2003); *see also Fal-Meridian, Inc. v. U.S. Dep't of Health & Human Servs.*, 604 F.3d 445, 447–49 (7th Cir. 2010).

"The standard of care imposed by these 'as is possible' and 'adequate supervision' regulations has been consistently interpreted by the DHHS and federal courts as a 'reasonableness' standard." *Cedar Lake Nursing Home v. U.S. Dep't of Health & Human Servs.*, 619 F.3d 453, 457 (5th Cir. 2010). The DAB has interpreted § 483.25(h) to place "a continuum of affirmative duties on a facility" to "determine whether any condition exists in the environment that could endanger a resident's safety" or "take action to protect residents from the danger posed by that condition." *Maine Veterans' Home – Scarborough*, 2005 WL 1164060, No. 1975, *4 (DAB 2005). "Whether

supervision is 'adequate' depends on the resident's ability to protect himself or herself from harm." *Golden Living Ctr – Riverchase*, No. 2314, *5 (DAB 2010). The regulation "require[s] the facility to take all reasonable steps to ensure that a resident receives supervision . . . that meet[s] his or her assessed needs and mitigate[s] foreseeable risks of harm from accidents." *Lake Park Nursing & Rehabilitation Ctr.*, 2006 WL 2382924, No. 2035, at *4 (DAB 2006). "A facility is permitted the flexibility to choose the methods it uses to prevent accidents, but the chosen methods must constitute an 'adequate' level of supervision under all the circumstances." *Windsor Health Care Ctr.*, 2003 WL 23142160, No. 1902, *3 (DAB 2003).

This court has affirmed the DAB's interpretation that the key consideration under the regulation is whether a facility has "take[n] all reasonable precautions against residents' accidents." *Woodstock Care Ctr. v. Thompson*, 363 F.3d 583, 589 (6th Cir. 2003); *see also Ashbury Center v. United States Department of Health & Human Services*, 77 F. App'x 853, 857 (6th Cir. 2003) (upholding the ALJ's finding of inadequate supervision when an entire corridor was left unsupervised for indefinite periods of time, and "two nursing assistants were off the floor during [a resident's] fall and the one remaining nurse was unable to monitor [the resident] as closely as was necessary."); *Clermont Nursing & Convalescent Center v. Leavitt*, 142 F. App'x 900, 904 (6th Cir. 2005) (upholding finding of inadequate supervision when surveyors noted an improperly affixed waist restraint that could have led the patient to injure herself). This analysis requires the DAB to "specifically look[] at whether each resident had received adequate supervision or assistance." *Clermont Nursing*, 142 F. App'x at 904. That a facility must take all reasonable precautions does not mean, however, that a facility may be penalized for not considering one specific type of preventive measure not required in the text of the regulation.

Here, CMS pointed to the resident's unsupervised falls as evidence that Mountain View was failing to take all reasonable precautions against residents' accidents. Factually, this seems evident. However, the ALJ and DAB did not point to the totality of the circumstances, including the continuing falls, and conclude that Mountain View had not taken all reasonable steps. Rather, they specifically concluded that in order to comply with the regulation Mountain View, and in turn all skilled nursing facilities housing ACUs where patients were falling, was required to consider additional staffing. This requirement was not included in the regulation nor in CMS's State Operations Manual on which it relies. The SOM interprets the regulations but is not a substantive or legislative rule. The SOM, under F-Tag 323, defines "adequate supervision" as "based on the individual resident's assessed needs and identified hazards in the resident environment. Adequate supervision may vary from resident to resident and from time to time for the same resident." (CA6 R. 15, Pet'r Am. App., SOM, PageID 96, 100.) As defined by the SOM, an "unavoidable accident" is an accident that occurred despite efforts to "[i]dentify environmental hazards," "[e]valuate/analyze the hazards and risks," "[i]mplement interventions, including adequate supervision, consistent with the resident's needs, goals, plan of care, and current standards of practice in order to reduce the risk of an accident," and "[m]onitor the effectiveness of the interventions and modify the interventions as necessary, in accordance with current standards of practice." (*Id.* at 95.)

The parties do not dispute that a fall is an "accident" within the scope of the regulation, nor that Mountain View had Fall Management Guidelines in place. The Guidelines require Mountain View to determine the resident's risk for falls prior to admission, initiate the Immediate Plan of Care at Risk-Falls Risk, and have its interdisciplinary team ("IDT") evaluate the residents' care plans after a fall. ***(Id.)*** Following a resident's fall: [t]he licensed nurse assesses the resident for

injuries . . . and provides necessary treatment," "[a]ppropriate interventions are implemented," and the "[c]are plan is updated." (*Id.*; *see also id*. at 596 (decision tree noting fall-risk/post-fall-assessment process and requirements for review and update of care plan, completing relevant reports such as the post-fall investigation summary, and IDT review to determine an additional needs).) Notably, Mountain View's policy mirrors the procedures the SOM describes as "proper actions following a fall." (CA6 R. 15, Pet'r Am. App., SOM, PageID 103.) The Quality Assurance ("QA") committee then uses this information "to identify systemic trends and patterns related to resident falls and appropriate plans of action." (CA6 R. 18, Resp't App., Falls Management Clinical Guidelines, PageID 595.)

Instead, CMS determined that Mountain View was not substantially compliant with § 482.25(h) based on the surveyors' findings that Mountain View had "failed to provide supervision and effective interventions to prevent falls for five [ACU] residents." (CA6 R. 18, Resp't App., Statement of Deficiencies, PageID 103.) CMS's evidence of noncompliance focused on the fact that many of the falls were unwitnessed by staff, thereby making it "obvious" that the facility should consider additional staffing as a part of taking all reasonable precautions to prevent such falls.

This "application" of agency guidance was arbitrary and capricious. Nowhere in the regulation or SOM is a facility required to specifically consider additional staffing to satisfy its duty to provide "adequate supervision." CMS argues that we should nevertheless uphold its determination that Mountain View violated the regulation because—as the DAB and ALJ concluded—adequate supervision "obvious[ly]" requires a facility to evaluate staffing. (*Id.*) But, contrary to CMS's contention, supervision and staffing are not synonymous. Supervision as an intervention refers to actions undertaken by facility staff to prevent accidents. These interventions

might include implementing a regular toileting schedule to eliminate a resident's desire to go to the restroom alone, adding additional check-ins on a resident's room, and assisting with eating, bathing, or other daily activities. Although staff are needed to implement these interventions, and a facility can be cited for inadequate supervision where it lacks staff to effectively execute the interventions set forth in a resident care plan, CMS only identified one instance where Mountain View did not have sufficient staff to effectively implement resident care plans. This instance occurred when, at a time when only two staff were present and each was attending to another resident, no staff were available to attend to a third resident's call alarm immediately.

Whether Mountain View was in compliance with § 483.25(h) is not the question before this court. Rather, the narrow question is whether the ALJ and DAB were correct in holding that CMS could properly asses a CMP against Mountain View solely for failing to consider adding additional staffing to the ACU. Because consideration of staffing is outside the scope of the regulation and unfairly surprised Mountain View, the ALJ and DAB's basis for finding Mountain View not in substantial compliance with § 483.25(h) was arbitrary and capricious. While the ALJ's ultimate outcome may have been correct, it is clear that the reasoning was not.

3. F353: Violation of 42 C.F.R. § 483.30(a)

In 2014, § 483.30(a) ("Nursing Services") required a facility to "provide services by sufficient numbers of each of the following types of personnel on a 24–hour basis to provide nursing care to all residents in accordance with resident care plans: (i) [e]xcept when waived under paragraph (c) of this section, licensed nurses; and (ii) [o]ther nursing personnel."

Because "sufficient numbers" is ambiguous, and CMS has not set forth a minimum staffing level in any interpretive guidance, the ALJ looked to a Tennessee regulation setting minimum staffing requirements for ACUs in the state. "[I]t is sufficient to recognize that the Tennessee

regulation establishes a standard of practice in that state for specific minimum level of staffing for an ACU. Therefore, falling below the minimum staffing specified in Tennessee . . . is good evidence of a deviation from the standard of practice in that state." (*Id.*) The Tennessee regulation requires different direct-care hours for nursing staff and general staff. Tenn. Dep't of Health, Ch. 1200-08-06-.07(9). "The designated units shall provide a minimum of 3.5 hours of direct care to each resident every day including .75 hours of licensed nursing personnel time. Direct care shall not be limited to nursing personnel time and may include direct care provided by dietary employees, social workers, administrator, therapists and other care givers, including volunteers." *Id.*

The ALJ, however, conflated the standard for direct care and the licensed nursing care requirement. The federal regulation requires facilities to maintain sufficient *nursing* care. § 483.30(a). Indeed, the title of the section is "nursing services." During the relevant time period under assessment, Mountain View complied with the required .75 hours of licensed nursing personnel time under Tennessee regulations. Mountain View maintained two LPNs, one for each wing of the ACU, as well as at least two CNAs, one for each wing, at all times in the ACU. The ALJ's finding that Mountain View failed to satisfy the Tennessee standard for direct care for each resident, providing only 3.16 hours of direct care, was not the appropriate standard even under the selected Tennessee regulation. Tennessee standard for direct care includes providers and services that fall outside of the federal regulations requirement to provide "sufficient numbers of . . . other nursing personnel." § 483.30(a).

The ALJ did not rely exclusively on his finding that Mountain View did not meet the Tennessee guidelines for direct care. However, substantial evidence does not support the conclusion that Mountain View failed to provide "sufficient numbers of [nursing] personnel on a

24–hour basis to provide nursing care to all residents in accordance with resident care plans." CMS only identified one instance where Mountain View did not have sufficient staff to effectively implement resident care plans. This instance occurred when, at a time when only two nurses were present and each was attending to another resident, no staff was available to attend to a third resident's call alarm immediately. Additionally, an immediate response is not required by the regulations, only sufficient nursing staff to provide care in compliance with the residents' care plans. CMS failed to provide evidence to support the determination that Mountain View did not provide sufficient nursing personnel. These errors resulted in an arbitrary and capricious determination that Mountain View was not in substantial compliance with § 483.30(a)'s nursing-staffing requirements.

4. F490: Violation of 42 C.F.R. § 483.75

Section 483.75 is a catchall provision that requires a facility to "be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident." "An administrative deficiency is a derivative finding, based on the presence of other deficiencies." *Ashbury Ctr. v. U.S. Dep't of Health & Human Servs.*, 77 F. App'x 853, 857 (6th Cir. 2003). To support a finding of noncompliance under § 483.75, the agency needs to show "that conduct supporting breaches of other regulations also supports an 'infer[ence]' that a facility's problems were 'systemic.'" *Life Care Ctr. Tullahoma v. U.S. Dep't of Health & Human Servs.*, 453 F. App'x 610, 617 (6th Cir. 2011) (quoting *Britthaven, Inc.*, 2006 WL 786659, No. 2018 (DAB 2006)).

In support of this allegation, the Statement of Deficiencies found that Mountain View "failed to ensure a system was in place to assess residents at risk for falls for appropriateness of interventions; ensure adequate staff were available to supervise residents; and ensure a safe

environment for residents at risk for falls on the Alzheimer's Care Unit." (CA6 R. 18, Resp't App., Statement of Deficiencies, PageID 165.) Further, it concluded that the facility's "failure to ensure sufficient staffing on the ACU resulted in the large number of witnessed and unwitnessed falls, on the unit." (*Id.*) The surveyors determined that "the facility did not implement appropriate interventions related to causes of falls taking into consideration environmental hazards, equipment maintenance and safety, and housekeeping processes. The facility failed to ensure appropriate assistive devices implemented were individualized and safe for the resident, including Broda chairs, geri chairs, seat belts, and bolsters." (*Id.* at 166.)

The administration requirement is derivative, meaning that compliance with it is dependent on compliance with the other cited regulations, and vice versa. The ALJ relied on its finding that Mountain View failed to substantially comply with its responsibility to prevent accidents under § 483.25(h) to find Mountain View not substantially compliant with the administration requirement. Because, as explained earlier, the application of the regulation was arbitrary and capricious and the ALJ finding was not supported by substantial evidence, we also conclude that the ALJ's determination that Mountain View violated § 483.75 was not supported by substantial evidence.

5. F501: Violation of 42 C.F.R. § 483.75(i)

In 2014, under § 483.75(i), the facility "must designate a physician to serve as medical director," and the medical director is responsible for "(i) [i]mplementation of resident care policies; and (ii) [t]he coordination of medical care in the facility." The section itself, as explained by the catchall provision discussed above, seeks to encourage a facility to "effectively and efficiently" use its resources "to maintain the highest practicable physical, mental, and psychosocial well-being of each resident." 42 C.F.R. § 483.75 (as effective 2014).

What is required for the medical director to "implement[] . . . resident care policies" is ambiguous. For example, the American Heritage Dictionary defines "implement" as "to put into practical effect; carry out." *Implement*, American Heritage Dictionary (2d ed. 1982). And the Oxford English Dictionary defines implement as "to complete, perform, [or] carry into effect. *Implement*, Oxford English Dictionary (2d ed. 1989). Given the lack of clarity that these definitions offer =, we look to the agency's interpretation of the regulation.

The DAB, in *Western Care Management Corp.*, 2004 WL 1235824, No. 1921, *56 (DAB 2004), stated that "CMS must do more than show the existence of other deficiencies in order to establish noncompliance with section 483.75(i)(2)."

> The regulation states that a medical director is "responsible for" implementation of care policies and coordination of medical care. To say, in this context, that the medical director is "responsible" for these things is to imply that he or she has a duty to perform certain actions in a satisfactory manner or to take steps to ensure that appropriate measures are taken by others. In its post-hearing brief, CMS did not identify a specific instance in which the medical director's actions or inaction with respect to a resident, or to the resident community at large, resulted in or contributed to a failure to implement care policies. Nor did CMS identify an instance in which the medical director failed to coordinate medical care under circumstances where coordination by the medical director was necessary or required. Because it is conceivable that deficiencies may exist despite a medical director's best and reasonable efforts to oversee and supervise the medical care in the facility, the mere assertion by CMS that deficiencies were found to exist on the medical director's watch is insufficient to establish that the medical director failed to assume the specified responsibilities.

Id. (footnotes omitted).

CMS, in the Statement of Deficiencies, alleged that Mountain View's Medical Director, Donald Vollmer, "failed to ensure [Mountain View's] fall policy and procedures were implemented." (CA6 R. 18, Resp't App., Statement of Deficiencies, PageID 168.) However, the findings are based solely on the fact that the five residents fell. CMS does not provide evidence for its conclusion that the fall policy and procedures were not being implemented by Vollmer other

than the falls. Similar to *Western Care Management Corp*., "CMS did not identify a specific instance in which the medical director's actions or inaction with respect to a resident, or to the resident community at large, resulted in or contributed to a failure to implement care policies." 2004 WL 1235824, at *56. Because the ALJ solely relied on the "mere assertion by CMS that deficiencies were found to exist on the medical director's watch," *id.*, without any independent analysis, to conclude that Vollmer was not in substantial compliance with the regulation, the ALJ and DAB's determination that Mountain View was not in substantial compliance is not supported by substantial evidence.

6. F520: Violation of 42 C.F.R. § 483.75(o)(1)

In 2014, under § 483.75(o)(1), a facility "must maintain a quality assessment and assurance committee consisting of – (i) [t]he director of nursing services; (ii) [a] physician designated by the facility; and (iii) [a]t least 3 other members of the facility's staff."

CMS's Statement of Deficiencies seeks to go beyond subsection 1, and further relies on subsection 2 requiring that the quality assessment and assurance committee "(i) [m]eet[] at least quarterly to identify issues with respect to which quality assessment and assurance activities are necessary; and (ii) [d]evelop[] and implement[] appropriate plans of action to correct identified quality deficiencies." § 438.75(o)(2). Specifically, CMS found that Mountain View's QA committee "failed to implement an effective action plan to address staff not following the facility's policy and procedures to prevent falls," and "failed to ensure an effective system for management of falls." (CA6 R. 18, Resp't App., Statement of Deficiencies, PageID 171.) The Statement of Deficiencies does not allege any noncompliance with subsection 1 regarding the makeup of the QA committee, rather it focuses on Mountain View's Fall Management Guidelines and the QA committee's review of falls in the ACU. CMS alleged that Mountain View failed to develop and

implement appropriate plans of action to prevent additional resident falls despite evidence showing that Mountain View reviewed the fall data at each monthly QA committee meeting and implemented an in-service education program for its staff regarding falls.

The ALJ concluded that Mountain View violated § 483.75(o)(1)—not § 483.75(o)(2)—even though Mountain View had a QA committee with the director of nursing services, a facility designated physician, and three other staff members. CMS did not present any evidence of a violation of § 483.25(o)(1), and the conclusion that Mountain View was not in substantial compliance was contrary to the evidence.

Even if CMS had alleged noncompliance with § 483.75(o)(2), CMS's interpretation of the regulation constitutes unfair surprise and was arbitrary and capricious. Relying on the State Operations Manual, in *Jewish Home of Eastern Pennsylvania*, 2011 WL 3251313, No. 2380, at *2 (DAB 2011), the DAB stated that "quality assessment" means "an evaluation of a process and/or outcomes of a process to determine if a defined standard of quality is being achieved." Moreover, a QA committee should "review facility records and information, identify potential and actual quality deficiencies, and develop corrective action plans." *Alexandria Place*, No. 2245, *14 (DAB 2009).

Here, Mountain View presented evidence from its QA meetings where the committee reviewed facility records regarding falls, identified potential and actual deficiencies, and developed corrective-action plans including auditing its staff to ensure interventions were being correctly implemented and providing additional staff education. The ALJ's and DAB's conclusion that Mountain View was not in substantial compliance with the regulation because the QA committee did not specifically consider adding additional staff constitutes unfair surprise and an unreasonable interpretation of the regulation. The regulation does not require a QA committee to

evaluate or implement any particular corrective-action plan, nor require a QA committee to specifically consider any particular interventions. Because the ALJ and DAB erred in concluding that a facility was required to separately consider additional staffing to comply with this regulation, the determination that Mountain View was not in substantial compliance was arbitrary and capricious.

IV. CONCLUSION

For the foregoing reasons we vacate the DAB's determination and remand for further consideration of whether the surveyor's findings of violations of 42 C.F.R. §§ 483.30(a) and 483.75 are sufficient by themselves to support CMS's finding of immediate jeopardy and, therefore, also sufficient to uphold the CMP.

CLAY, Circuit Judge, concurring in part and dissenting in part. Petitioner Golden Living Center – Mountain View ("Mountain View") is a skilled nursing facility in Tennessee that participates in federal Medicare and Medicaid programs. In early 2014, after an inspection of Mountain View's facilities revealed that five residents had fallen over forty times during a four-month period, the Centers for Medicare and Medicaid Services ("CMS") imposed a civil monetary penalty ("CMP"), totaling $621,250, based on Mountain View's purported failure to comply with seven federal regulatory requirements for such facilities. Mountain View has requested this Court to review the decision by the Department of Health and Human Services' Departmental Appeals Board ("DAB") affirming the CMP. Because I would affirm the decision of the DAB as to three of Mountain View's claims, I dissent in part.

BACKGROUND

As a skilled nursing facility participating in Medicare and Medicaid, Mountain View must comply with the provisions of 42 C.F.R. § 483. In order to ensure facilities' compliance, CMS authorizes state agencies to survey facilities and document instances of noncompliance, identified as "deficiencies." 42 C.F.R. § 488.404(b). When a survey uncovers deficiencies, the surveyors assign those deficiencies a severity level. The highest severity level is noncompliance that causes "immediate jeopardy to resident health or safety," (ALJ Decision, Pet'r App. at 30 n.4), which is found when noncompliance "has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident," 42 C.F.R. § 488.301. Depending on the severity of noncompliance, CMS may impose a range of CMPs on a facility. *Id.* § 488.438(a)(1).

A facility may seek review of a CMP by an administrative law judge ("ALJ"), who conducts a *de novo* review to decide "whether the evidence as it [was] developed before the ALJ supports the finding of noncompliance, not how CMS, or the facility, evaluated the evidence as it

stood at whatever times CMS or the facility made their assessments." *Life Care Ctr. of Bardstown*, DAB No. 2479, 2012 WL 5290709, at *27 (2012), *aff'd Life Care Ctr. of Bardstown v. Sec'y of Health & Human Servs.*, 535 F. App'x 468 (6th Cir. 2013). A facility may appeal the ALJ's decision to the DAB, which will consider whether the ALJ's findings of fact were "supported by substantial evidence in the record as a whole" and whether her legal conclusions were "erroneous." *Id.* at *4 (citation omitted). The facility may then seek judicial review of the DAB's decision. 42 U.S.C. § 1320-7a(e) ("Any person adversely affected by a determination of the Secretary . . . may obtain review of such determination in the United States Court of Appeals for the circuit in which the person resides . . ." (incorporated by § 1395i-3(h)(2)(B)(ii)(I))).

As the majority notes, the factual background of this case is nearly undisputed. Tennessee state surveyors completed a survey of Mountain View in April 2014, and found that it had violated six sets of regulations: (1) 42 C.F.R. §§ 483.10(d)(3) and 483.20(k)(2) ("Tag F280," or "F280"), pertaining to the development and revision of care plans for facility residents; (2) § 483.25(h) ("Tag F323," or "F323"), pertaining to the supervision and devices necessary to prevent accidents; (3) § 483.30(a) ("Tag F353," or "F353"), pertaining to nursing staffing levels; (4) § 483.75 ("Tag F490," or "F490"), pertaining to facility administration; (5) § 483.75(i) ("Tag F501," or "F501"), pertaining to the appointment of a facility medical director; and (6) § 483.75(o)(1) ("Tag F520," or "F520"), pertaining to the appointment and functioning of a facility Quality Assurance Committee. The surveyors' determinations were based heavily on their findings that five residents of Mountain View's Alzheimer's Care Unit had fallen more than forty times during a period of four months, in instances largely unwitnessed by Mountain View staff. The surveyors concluded that these falls placed the five residents in immediate jeopardy. Based on these determinations, CMS ultimately imposed a CMP totaling $621,250.

Mountain View sought ALJ review of the CMP. The ALJ affirmed CMS's findings and the CMP, but on the basis that Mountain View should have considered increasing staffing levels in response to the residents' falls, and that it did not do so. Mountain View appealed, conceding that the ALJ's factual findings were nearly entirely correct, but arguing that the applicable regulations did not require it to consider increasing staffing levels. The DAB affirmed the ALJ's decision. Mountain View then brought this appeal.

DISCUSSION

As the majority correctly notes, our review of DAB decisions is highly deferential. *Woodstock Care Ctr. v. Thompson*, 363 F.3d 583, 588 (6th Cir. 2003). We treat prior factual findings as conclusive "if supported by substantial evidence on the record considered as a whole." *Id.* (quoting 42 U.S.C. § 1320a-7a). With regard to the law, we defer to an agency's interpretation of its own genuinely ambiguous regulations unless the agency's interpretation "does not reflect [its] authoritative, expertise-based, 'fair[, or] considered judgment.'" *Kisor v. Wilkie*, 139 S. Ct. 2400, 2414 (2019) (second alteration in original) (quoting *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 155 (2012)). Under the Administrative Procedures Act, we will set aside an agency action, finding, or decision only if it is arbitrary and capricious—that is, "if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

In reviewing CMS' decision to impose a civil monetary penalty on Mountain View, both the ALJ and the DAB applied the burden-shifting framework laid out in *Hillman Rehabilitation*

Center, DAB No. 1611, 1997 WL 123708 (1997). Under that framework, the agency must first come forward with evidence demonstrating a *prima facie* case of a regulatory violation. *Id.* at *4. Once it has done so, the burden of persuasion shifts to the facility to "prove by a preponderance of the evidence on the record as a whole that it is in substantial compliance with the relevant statutory and regulatory provisions." *Id.*

Although I concur in the majority's discussion and disposition of the claims brought by Mountain View under 42 C.F.R. §§ 483.10(d)(3) and 483.20(k)(2); § 483.75(i); and § 483.75(o)(1), for the reasons that follow, I disagree with the majority's analysis of Mountain View's claims under § 483.25(h), pertaining to the supervision and devices necessary to prevent accidents; § 483.30(a), pertaining to nursing staffing levels; and § 483.75, pertaining to facility administration. Put simply, I do not agree that the DAB's interpretation of these provisions was arbitrary and capricious, and, accordingly, I would find that Mountain View's violation of these provisions led to the injuries of its residents in its Alzheimer's Care Unit.

I. Violation of 42 C.F.R. § 483.25(h) (F323)

As the majority correctly explains, in early 2014, five residents of Mountain View's Alzheimer's Care Unit suffered a series of falls—more than forty in total—that were largely unwitnessed by staff. At the time of these events, 42 C.F.R. § 483.25(h) required Mountain View, among other things, to ensure that "[e]ach resident receive[d] adequate supervision and assistance devices to prevent accidents." The parties agree that the residents' falls were accidents. They dispute only whether Mountain View's residents received "adequate supervision."

I agree with the majority that the term "adequate supervision" is ambiguous. In light of that ambiguity, CMS has explained that "adequate supervision" is defined "based on the individual resident's assessed needs and identified hazards in the resident environment. Adequate

supervision may vary from resident to resident and from time to time for the same resident." (State Operations Manual, Pet'r App. at 96; *see also id.* at 100.) When considering "[w]hether supervision is 'adequate,'" the answer "depends . . . on the resident's ability to protect himself or herself from harm." *Lake Park Nursing & Rehabilitation Ctr.*, DAB No. 2035, 2006 WL 2382924, at *4 (2006); *see also Woodstock Care Ctr.*, DAB No. 1726, at *30 (2000), *aff'd Woodstock*, 363 F.3d 583. In prior decisions, the DAB has repeatedly noted that § 483.25(h) "require[s] the facility to take all reasonable steps to ensure that a resident receives supervision . . . that meet[s] his or her assessed needs and mitigate[s] foreseeable risks of harm from accidents." *Id.*; *see also Woodstock Care Ctr.*, DAB No. 1726, at *25 ("[T]he quality of care provisions do impose an affirmative duty to provide services (in this case, supervision and devices to prevent accidents) designed to achieve [favorable] outcomes to the highest practicable degree."). This Court has affirmed the application of that standard, *see Woodstock*, 363 F.3d at 589–90, and further noted that "the question of whether the defendant in question took all reasonable precautions to prevent accidents is 'highly fact-bound and can only be answered on the basis of expertise in nursing home management. As such, it is a question the resolution of which we defer to the expert administrative agency, the [Department of Health and Human Services,]'" *Clermont Nursing & Convalescent Ctr. v. Leavitt*, 142 F. App'x 900, 903 (6th Cir. 2005) (alteration in original) (quoting *Woodstock*, 363 F.3d at 589).

The majority does not dispute that CMS made a *prima facie* showing that Mountain View violated § 483.25(h) by providing evidence of the residents' falls and the circumstances surrounding those falls. However, it goes on to conclude that the DAB's determination that

Mountain View had not met its burden to show substantial compliance with the regulation was arbitrary and capricious. I disagree.

The evidence before the ALJ and DAB showed that Mountain View did take some steps to increase the supervision of residents after falls. However, residents continued to fall despite these interventions. (ALJ Decision, Pet'r App. at 39–55 (detailing each resident's falls, interventions taken, and continued falls); *id.* at 76 (noting that although Mountain View was "very proactive in addressing the falls . . . when the number of falls continued to increase, particularly after December 2013 when first identified by the QA committee and management, it was a clear signal that the root cause of the increase in falls had not been fully identified and addressed."). This put Mountain View on notice that these residents did not have the "ability to protect [themselves] from harm" even with these interventions, and thus, that the interventions were inadequate. *See Lake Park*, 2006 WL 2382924, at *4.

At that point, Mountain View was required to "take all reasonable steps to ensure" that these residents received supervision adequate to meet their assessed needs and "mitigate foreseeable risks of harm from accidents." *Id.* (citing *Woodstock*, 363 F.3d at 590). Basic common sense suggests "all reasonable steps" includes considering increasing staffing levels in order to enable more constant supervision. While actually increasing staffing levels may not necessarily be a "reasonable step," given the costs and burdens involved, considering increasing staffing levels imposes little cost or burden on facilities and is clearly reasonable.

The majority points out that "supervision and staffing are not synonymous" and that in order to show "adequate supervision," Mountain View could have simply implemented interventions like a regular toileting schedule, additional check-ins with residents, or greater assistance with daily activities, rather than considering increasing staffing levels. *Ante* at 15. It is

true that these are surely reasonable steps Mountain View could have taken to ensure adequate supervision. But these are not *all* of the reasonable steps Mountain View could have taken, especially since most of these interventions had already proven ineffective in stemming its residents' falls. And the simple fact that there may have been other reasonable steps Mountain View could have taken does not suggest that the DAB acted arbitrarily or capriciously in determining that one reasonable step Mountain View needed to take was assessing the adequacy of its staffing levels. Given our deferential standard of review, this Court should defer to that decision. *Clermont Nursing*, 142 F. App'x at 903.

II. Violation of 42 C.F.R. § 483.30(a) (F353)

In 2014, 42 C.F.R. § 483.30 required facilities to "have sufficient nursing staff to provide nursing and related services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care." In particular, facilities were to "provide services by sufficient numbers of each of the following types of personnel on a 24-hour basis to provide nursing care to all residents in accordance with resident care plans: (i) . . . licensed nurses; and (ii) [o]ther nursing personnel." 42 C.F.R. § 483.30(a).

The majority concludes that the ALJ's determination that Mountain View was not in substantial compliance with § 483.30(a)'s nursing staffing requirements was arbitrary and capricious. I disagree. As an initial matter, CMS made a *prima facie* case by presenting evidence that residents continued to fall, in events unwitnessed by staff, despite Mountain View's initial interventions. *See, e.g.*, *Community Northview Care Ctr.*, DAB No. 2295, 2009 WL 5947376, at *16 (2009) (finding that a *prima facie* deficiency can be established based on evidence of failure to meet care needs, whether or not they are identified in individual care plans, because "[t]he staff

must comply with the individual plans but must also provide all services required to meet the standard of 'highest practicable physical, mental, and psychosocial well-being of each resident'" (citing § 483.25)). While Mountain View could still prove otherwise, evidence that five residents fell over forty times in a period of four months is surely enough to initially suggest that Mountain View did not have sufficient nursing staff to achieve the "highest practicable physical, mental, and psychosocial well-being" outcomes for each resident. Based on this evidence, it was not arbitrary and capricious for the DAB to find that CMS had made out a *prima facie* case.

Turning then to whether Mountain View demonstrated its substantial compliance with § 483.30(a), I conclude that it did not. When considering what was required of Mountain View under § 483.30(a), the majority rightly notes that what constituted "sufficient numbers" of licensed nurses and nursing personnel is ambiguous. DAB decisions have made clear that "compliance with state staffing requirements" does not necessarily "satisf[y] the federal staffing regulation. . . . The federal focus is on care outcome, not satisfaction of a numerical threshold." *The Windsor House*, DAB No. 1942 (2004). CMS concluded that Mountain View had failed to comply with § 483.30 based on its findings that a number of the residents' falls went unobserved, that groups of residents were frequently left without supervision, that residents were not consistently immediately responded to when their call lights or attendant alarms went off, and that staff reported their perception of insufficient staffing levels in interviews.

The ALJ here looked to Tennessee regulations as instructive as to whether Mountain View complied with federal regulations. State regulations required facilities that provide services to residents with Alzheimer's—as Mountain View does—to "provide a minimum of 3.5 hours of direct care to each resident every day including .75 hours of licensed nursing personnel time," with "direct care" including care "provided by dietary employees, social workers, administrator,

therapists and other care givers, including volunteers." Tenn. Dep't of Health, Ch. 1200-08-06-.07(9). But the ALJ did not treat Mountain View's compliance with that standard as dispositive of its federal regulatory compliance. Instead, the ALJ noted that the Tennessee regulation "establishes a standard of practice in that state for [a] specific minimum level of staffing," and so "falling below the minimum staffing specified . . . is good evidence of a deviation from the standard of practice in that state." (ALJ Decision, Pet'r App. at 76.) The ALJ then found that Mountain View had failed to consistently provide the required 3.5 hours of direct care, and that it had likewise failed to substantially comply with the federal regulation. The DAB affirmed.

The majority correctly concludes that the evidence suggests that Mountain View did meet the Tennessee regulation's requirement of .75 hours of licensed nursing personnel time per resident per day. But both the ALJ and the DAB were very clear that Mountain View more broadly failed to consistently meet the 3.5 hours of direct care requirement. And the state regulation provides that the .75-hour requirement is only for "licensed nursing personnel," Tenn. Dep't of Health, Ch. 1200-08-06-.07(9), which corresponds with only one part of the federal regulation, 42 C.F.R. § 483.30(a)(1)(i). The other part of that regulation calls for sufficient "[o]ther nursing personnel." *Id.* § 483.30(a)(1)(ii). "Other nursing personnel" is not defined, and it could reasonably be understood to describe caregivers including "dietary employees, social workers, administrator, therapists and other care givers, including volunteers." Tenn. Dep't of Health, Ch. 1200-08-06-.07(9); *see, e.g.*, *Nursing*, Oxford English Dictionary (3d. ed. 2003) ("To care for (a person) during sickness or infirmity; to help through an illness, etc."). Thus, the DAB did not act arbitrarily or

capriciously in determining that the federal regulation called for at least 3.5 hours of time from other nursing personnel.

Moreover, whether Mountain View complied with the Tennessee regulation is not dispositive. Under federal regulations, Mountain View cannot necessarily show its substantial compliance by demonstrating that it met Tennessee's "numerical threshold," but must instead show that it met the appropriate "care outcome," *Windsor House*, DAB No. 1942, namely, that the facility "attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care," 42 C.F.R. § 483.30. As before, Mountain View was on notice that it was not achieving the "highest practicable physical, mental, and psychosocial well-being" outcomes for each resident when they continued to fall despite its early interventions. While hiring additional staff itself may not have been "practicable" in order to better residents' well-being, Mountain View cannot show that considering hiring staff was not practicable or that this was not necessary to ensure that nursing staffing levels were sufficient. The DAB did not act arbitrarily or capriciously in concluding that § 483.30(a) required Mountain View to consider increasing staffing levels.

III. Violation of 42 C.F.R. § 483.75 (F490)

As in effect in 2014, 42 C.F.R. § 483.75 required a facility to "be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident." As the majority acknowledges, a deficiency in complying with this regulation "is a derivative finding, based on the presence of other deficiencies." *Ashbury Ctr. v. U.S. Dep't of Health & Human Servs.*, 77 F. App'x 853, 857 (6th Cir. 2003). In order to show a violation, CMS was required to show "that conduct supporting breaches of other regulations also supports an 'infer[ence]' that a facility's

problems were 'systemic.'" *Life Care Ctr. Tullahoma v. U.S. Dep't of Health & Human Servs.*, 453 F. App'x 610, 617 (6th Cir. 2011) (alteration in original) (quoting *In re Britthaven, Inc.*, DAB No. 2018 (2006)).

CMS concluded that Mountain View violated this regulation based on its findings that Mountain View, among other things, had failed to ensure "adequate staff were available to supervise residents" resulting in a "large number of witnessed and unwitnessed falls," and had failed to "ensure a safe environment for residents at risk for falls on the Alzheimer's Care Unit," including by "implement[ing] appropriate interventions related to causes of falls taking into consideration environmental hazards, equipment maintenance and safety, and housekeeping processes." (Statement of Deficiencies, Resp't App. at 203–04.)

The majority concludes that the ALJ's determination that Mountain View violated § 483.75 was not supported by substantial evidence. I disagree. Because § 483.75 is derivative of the previously discussed regulations, I would rely on the evidence supporting the ALJ and the DAB's holdings that Mountain View violated both § 483.25(h), pertaining to adequate supervision, and § 483.30(a), pertaining to nursing personnel, to find that Mountain View violated § 483.75. Thus, we should also affirm the DAB's decision that Mountain View did not administer its facility in order to effectively achieve the highest practicable well-being for its residents under § 483.75.

CONCLUSION

For the reasons explained, this Court wrongly reverses the DAB's decision regarding §§ 483.25(h), 483.30(a), and 483.75. I would instead affirm as to these decisions and remand this case to the DAB for further consideration of whether these three violations are sufficient by themselves to ground CMS's finding of immediate jeopardy and, thus, also sufficient to uphold the CMP. I therefore dissent in part.