Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Blossom South Nursing and Rehabilitation Center
Docket No. A-14-41
Decision No. 2578
June 11, 2014

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Blossom South Nursing and Rehabilitation Center (Blossom South), a Rochester, New York skilled nursing facility (SNF), appeals the November 27, 2013 decision by an administrative law judge (ALJ) upholding the termination of Blossom South's Medicare participation based on the determination of the Centers for Medicare & Medicaid Services (CMS) that Blossom South was not in substantial compliance with Medicare participation requirements. *Blossom South Nursing & Rehab. Ctr.*, DAB CR3013 (2013) (ALJ Decision). The ALJ concluded that Blossom South was not in substantial compliance with 11 participation requirements and that CMS had authority to terminate Blossom South's Medicare participation based on its noncompliance with any one of those requirements.

On appeal, Blossom South disputes the ALJ's conclusion that it was not in substantial compliance with three of the 11 participation requirements. Blossom South does not specifically dispute the ALJ's conclusion that it was not in substantial compliance with the eight remaining participation requirements; however, Blossom South argues that the ALJ violated its due process rights in upholding the termination based on that noncompliance because CMS did not give it timely notice that the termination was based on survey findings with respect to those requirements.

For the reasons explained below, we conclude that Blossom South had timely notice that the termination was based on all 11 participation requirements. We further conclude that the ALJ did not err in concluding that Blossom South failed to comply substantially with all 11 participation requirements, including the three as to which Blossom South raises a dispute. Accordingly, we affirm the ALJ's decision upholding the termination.

Legal Background

To participate in the Medicare program, a SNF must be in "substantial compliance" with the requirements in 42 C.F.R. Part 483. 42 C.F.R. §§ 483.1, 488.400. Under agreements with the Secretary of Health & Human Services, state survey agencies conduct onsite surveys to verify compliance with the Medicare participation requirements. *Id.* §§ 488.10(a), 488.11; *see also* Social Security Act (Act) §§ 1819(g)(1)(A), 1864(a).[1] A state survey agency reports any "deficiencies" it finds in a document called a Statement of Deficiencies (SOD), which identifies each deficiency under its regulatory requirement and the corresponding "tag" number. A "deficiency" is any failure to comply with a Medicare participation requirement, and a SNF is not in "substantial compliance" when it has one or more deficiencies that have the potential for causing "more than minimal" harm to residents. 42 C.F.R. § 488.301 (also defining "noncompliance" as "any deficiency that causes a facility to not be in substantial compliance").

Surveyors categorize each deficiency by its level of "seriousness," which is a function of: (1) "severity" – that is, whether the deficiency has created a "potential for more than minimal harm," resulted in "actual harm," or placed residents in "immediate jeopardy"; and (2) "scope" – that is, whether the noncompliance is "isolated," constitutes a "pattern," or is "widespread." 42 C.F.R. § 488.404(b); State Operations Manual (SOM), CMS Pub. 100-07, Appendix (App.) P – Survey Protocol for Long Term Care Facilities, Part I, Chapter IV ("Deficiency Categorization") (available at http://www.cms.hhs.gov/Manuals/IOM/list.asp); 59 Fed. Reg. 56,116, 56,183 (Nov. 10, 1984)(scope and severity grid identifying remedies applicable to scope and severity level "D" (isolated deficiency posing no actual harm with potential for more than minimal harm that is not immediate jeopardy) through level "L" (widespread deficiency posing immediate jeopardy to resident health or safety))[2].

A participating SNF is subject to a standard survey at intervals of no less than 15 months (with a statewide average interval of 12 months) to ensure that identified deficiencies are corrected. Act § 1819(g)(2)(A); 42 C.F.R. § 488.308. A SNF is also subject to other types of surveys, including surveys to investigate a complaint that the facility is violating one or more participation requirements. 42 C.F.R. § 488.308.

[1] The current version of the Social Security Act can be found at http://www.socialsecurity.gov/OP_Home/ssact/ssact.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 42 U.S.C.A. Ch. 7, Disp Table.

[2] Scope and severity levels "A" through "C" on the grid constitute substantial compliance.

The Act requires that the Secretary "conduct a special focus facility program for enforcement of requirements for [SNFs] that the Secretary has identified as having substantially failed to meet applicable requirement[s] of this Act." Act § 1819(f)(8)(A). A certain number of SFFs are designated by each state from a list compiled by CMS of approximately 15 SNFs with the "worst compliance history" in the state. CMS Ex. 22 (CMS State Survey Letter S&C-08-02 (Nov. 2, 2007)) at 4. A SFF must be surveyed at least once every six months. Act § 1819(f)(8)(B). A SFF can "graduate from the designation of a SFF" when it has undergone two consecutive standard surveys with no deficiencies cited at a scope and severity level greater than "E" (widespread with potential for causing more than minimal harm that is not immediate jeopardy) and had no intervening complaint-related deficiencies cited at a scope and severity level greater than "E." CMS Ex. 22, at 2, note b.

A SNF found not to be in substantial compliance is subject to one or more enforcement remedies, including termination. 42 C.F.R. §§ 488.402, 488.406, 488.408. We set out the relevant statutory and regulatory provisions regarding termination in our analysis below.

Factual Background

Blossom South was designated a SFF on March 31, 2011. ALJ Decision at 2. In April 2013, CMS instructed state survey agencies to "[s]chedule a final 'last chance' onsite survey for those facilities that have been on the SFF list for more than 18 months and have failed to improve." CMS Ex. 5 (CMS State Survey Letter S&C:13-23-ALL (Apr. 5, 2013)), at 3. CMS stated that "a Medicare termination notice may be issued if the onsite survey does not reveal appropriate improvement or unless there is a major new development that CMS concludes is very likely to eventuate in timely and enduring improvement in the quality of care or safety." *Id.* By letter dated August 16, 2013, CMS advised Blossom South that a "last chance recertification survey" completed by the New York State Department of Public Health, the state survey agency, cited three deficiencies that exceeded the "E" level of scope and severity, consisting of one level "G" deficiency— noncompliance with section 483.25, and two level "F" deficiencies— noncompliance with sections 483.25(m)(2) and 483.35(i). CMS Ex. 3, at 1.[3] The letter continued: "Based on the survey of August 8, 2013, your facility has not graduated from the SFF program and is now subject to termination from the Medicare and Medicaid Programs. All regulatory references may be found in Part 42 of the Code of Federal Regulations." *Id.* Following this language, the letter stated:

[3] The August 16 letter states that it replaces CMS's August 15 termination letter containing "incorrect information concerning an IDR and an Alternative State Remedy." CMS Ex. 3, at 1. The language quoted here from the August 16 letter also appears in the August 15 letter.

IMPOSITION OF REMEDIES

TERMINATION OF PROVIDER AGREEMENT

> Your provider agreement in the Medicare and Medicaid programs will be terminated September 15, 2013. This action is mandated by the Social Security Act at §§ 1819(h)(2)(C) and 1919(h)(3)(D) and Federal regulations at 42 CFR §§ 488.412 and 488.456. . . .

CMS Ex. 3, at 2.

Blossom South received a SOD for the August 8, 2013 survey. Blossom South Request for Review (RR) at 1. In addition to the three deficiencies specified in CMS's August 16 letter, the SOD set out eight other deficiencies, involving sections 483.10(b)(4), 483.15(h)(2), 483.20(k)(3)(i), 483.25(d), 483.25(h), 483.60(b),(d) and (e), 483.70(h)(4), and 483.75(l)(1), that were identified as level "D" or level "E." The SOD also set out one deficiency identified as level "C," for which no remedy is authorized by the regulations. CMS Ex. 1. Blossom South filed a timely request for hearing pursuant to 42 C.F.R. Part 498. Both parties submitted written declarations of witnesses, only one of whom, Surveyor L.W., was cross-examined (by Blossom South). *See* ALJ Decision at 4; Hearing Transcript (Tr.).

The ALJ Decision

In her decision, the ALJ states that the "sole issue before me is whether, based on the survey ending August 8, 2013, the facility was in substantial compliance with Medicare program requirements." ALJ Decision at 5. The ALJ Decision sets forth the following "findings of fact/conclusions of law" (FFCLs):

A. The facility was not in substantial compliance with 42 C.F.R. §§ 483.10(b)(4), 483.15(h)(2), 483.20(k)(3)(i), 483.25(d), 483.25(h), 483.60(b), 483.70(h)(4), and 483.75(l)(1), and CMS may terminate its program participation based on any one of those deficiencies alone.

B. The facility was not in substantial compliance with 42 C.F.R. § 483.25 (Tag F309), because it did not provide R6 necessary care and services to address his missing, broken and decayed teeth, and his ill-fitting partial bridge, which left him unable to eat regular food and experiencing sporadic pain and discomfort.

C. The facility was not in substantial compliance with 42 C.F.R. § 483.25(m)(2) (Tag F333), because it did not ensure that staff administered narcotics as ordered; water had been substituted for morphine; and staff falsified medication administration

records, so that no reviewer could verify how much of a narcotic had been administered.

D. The facility was not in substantial compliance with 42 C.F.R. § 483.35(i) (Tag F371), because one of its cooks did not properly cool a roast she intended to serve to facility residents, and she plainly did not understand safe techniques for cooling foods. Further, surfaces used for food service were not kept clean and sanitary.

ALJ Decision at 5, 19, 23, 25.

Under FFCL A, the ALJ first observed that Blossom South's submissions did not address any of the eight level "D" and level "E" deficiency findings on which CMS's determination of noncompliance was based. ALJ Decision at 5. Thus, the ALJ stated, "[t]he unrebutted evidence … establishes that the facility was not in substantial compliance, and CMS was therefore authorized to impose a remedy, including termination." *Id*. at 5-6. The ALJ further stated that Blossom South "concedes that the statute and regulations authorize CMS to terminate a facility that is not in substantial compliance but argues that, '[w]hile those rules may apply generally[,] they do not apply here'…notwithstanding its ongoing substantial noncompliance[.]" *Id*. at 6, citing P. Post-hrg. Br. at 10. The ALJ rejected Blossom South's argument for reasons described in our discussion below. The ALJ proceeded to discuss the undisputed evidence regarding each of the eight unchallenged deficiency findings, prefacing her discussion with the following statement: "Deficiencies that pose the 'potential for causing more than minimal harm' are not trivial. To the contrary, as the following discussion shows, these purportedly 'lower level' deficiencies unquestionably endangered the health and safety of facility residents." ALJ Decision at 8-18. The ALJ then discussed at length each of her remaining FFCLs. *Id*. at 19-29.

Standard of Review

The Board's standard of review concerning a disputed finding of fact is whether the finding is supported by substantial evidence on the record as a whole. *Guidelines – Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's Participation in the Medicare and Medicaid Programs*, http://www.hhs.gov/dab/divisions/appellate/guidelines/prov.html. The Board's standard of review concerning a disputed conclusion of law is whether the conclusion is erroneous. *Id*.
Substantial evidence means "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Richardson v. Perales*, 402 U.S. 389, 401 (1971), quoting *Consolidated Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938). Under the substantial evidence standard, the Board does not re-weigh the evidence or overturn an ALJ's "choice between two fairly conflicting views" of the evidence; instead, the Board determines whether the contested finding could have been made by a reasonable factfinder "tak[ing] into account whatever in the record fairly detracts from the weight of

the evidence" upon which the ALJ relied. *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 488 (1951); *see also Golden Living Ctr. – Frankfort*, DAB No. 2296, at 9-10 (2009), *aff'd, Golden Living Ctr.- Frankfort v. Sec'y of Health & Human Servs.*, 656 F.3d 421 (6th Cir. 2011). With respect to allegations of procedural error, the Board reviews to determine whether the ALJ committed an error of procedure that resulted in prejudice (including an abuse of discretion under the law or applicable regulations). *Guidelines*.

Analysis[4]

A. CMS gave Blossom South timely and adequate notice that CMS was terminating Blossom South's Medicare participation based on all of the noncompliance found on the August 8, 2013 survey.

Blossom South asserts that the only basis for termination of which CMS's termination letter gave notice was Blossom South's alleged failure to graduate from the SFF program, which Blossom South maintains is not a legal basis for termination. According to Blossom South, CMS changed the basis for termination to Blossom South's alleged failure to comply substantially with Medicare participation requirements but CMS did not inform Blossom South of this change until CMS filed its prehearing brief. Blossom South takes the position that it did not have a reasonable opportunity to respond to what it views as new grounds for the termination, and was therefore deprived of due process, because the ALJ required the parties to file simultaneous prehearing briefs and then proceeded directly to hearing. RR at 13-16.

In support of its argument that the legal basis for the termination was its alleged failure to graduate from the SFF program rather than all of the noncompliance (with 11 participation requirements) found on the August 8, 2013 survey, Blossom South points to the part of the termination letter listing the three level "F" and "G" deficiency findings from that survey and stating, "Based on the survey of August 8, 2013, your facility has not graduated from the SFF program and is now subject to termination from the Medicare and Medicaid programs." RR at 14, quoting CMS Ex. 3, at 1. Blossom South asserts that it "reasonably believed that the termination was due to its purported failure to graduate from the SFF program based on" the three deficiencies identified. RR at 14.

We conclude that CMS's August 16 termination letter gave Blossom South timely and adequate notice that the termination was based on its failure to comply substantially with participation requirements, not on its failure to graduate from the SFF program. As a threshold matter, Blossom South could not reasonably have believed that its failure to

[4] We have fully considered Blossom South's arguments on appeal, although we do not specifically address all of them.

graduate from the SFF program was the legal basis for the termination since, as Blossom South acknowledges (RR at 16), there is no separate provision in the Act authorizing termination based on a facility's failure to graduate from the SFF program. Instead, the statutory and regulatory grounds for terminating a SFF, like any other SNF, are those set forth in the statutory and regulatory provisions cited in CMS's termination letter. Blossom South's "belief" is also not reasonable given the termination letter as a whole. As previously noted, under the captions "Imposition of Remedies" and "Termination of Provider Agreement," the letter states in relevant part: "Your provider agreement in the Medicare and Medicaid programs will be terminated September 15, 2013. This action is mandated by the Social Security Act at §§ 1819(h)(2)(C) and 1919(h)(3)(D) and Federal regulations at 42 CFR §§ 488.412 and 488.456." CMS Ex. 3, at 2. As explained below, the cited authorities include provisions that permit CMS to terminate a SNF's Medicare participation under the circumstances present in this case. By citing to these provisions, CMS gave adequate notice that it was terminating Blossom South's Medicare participation based on its noncompliance with Medicare participation requirements as evidenced by the 11 level "D" and higher deficiencies found by the August 8, 2013 survey.

Section 1819(h)(2)(C) of the Act, one of the two statutory provisions cited, sets out part of the enforcement process for assuring quality of care in SNFs.[5] The preceding subsections authorize the Secretary to impose remedies if the Secretary finds based on a survey (or finds pursuant to the recommendation of a State based on a survey) that the SNF no longer meets a participation requirement. *See* Act §§ 1819(h)(2)(A) , (B). Section 1819(h)(2)(C) then provides in pertinent part that the Secretary—

> may continue payments, over a period of not longer than 6 months after the effective date of the findings , under this title with respect to a skilled nursing facility not in compliance with a [participation requirement] [6], if—
>
> (i) the State survey agency finds that it is more appropriate to take alternative action to assure compliance of the facility with the requirements than to terminate the certification of the facility,
>
> (ii) the State has submitted a plan and timetable for corrective action to the Secretary for approval and the Secretary approves the plan of correction, ...

[5] Since Blossom South was a SNF, we quote only from section 1819(h)(2)(C), which applies to SNFs, and not from section 1919(h)(3)(D), a virtually identical provision that applies to nursing facilities.

[6] The actual language is "a requirement of section (b), (c), or (d)." Subsection (b) of section 1819 is titled "Requirements Relating to Provision of Services"; subsection (c) is titled "Requirements Relating to Residents' Rights"; and subsection (d) is titled "Requirements Relating to Administration and Other Matters."

Section 488.412 of 42 C.F.R., one of the two regulatory provisions cited, is captioned "Action when there is no immediate jeopardy" and states in relevant part: "If a facility's deficiencies do not pose immediate jeopardy to residents' health or safety, and the facility is not in substantial compliance, CMS or the State may terminate the facility's provider agreement or may allow the facility to continue to participate for no longer than 6 months from the last day of the survey if" the criteria for continuation of payment specified in the statute are met. 42 C.F.R. § 488.412(a). The section further provides: "If a facility does not meet the criteria for continuation of payment..., CMS will and the State must terminate the facility's provider agreement." *Id*. § 488.412(b). Finally, the section provides: "CMS terminates the provider agreement...if the facility is not in substantial compliance within 6 months of the last day of the survey." *Id*. § 488.412(d). The other regulatory provision cited in the termination letter, 42 C.F.R. § 488.456, is captioned "Termination of provider agreement" and states in relevant part: "CMS and the State may terminate a facility's provider agreement if a facility—(i) Is not in substantial compliance with the requirements of participation, regardless of whether or not immediate jeopardy is present; or (ii) Fails to submit an acceptable plan of correction within the timeframe specified by CMS or the State." *Id*. § 488.456(b).

These statutory and regulatory provisions mandate termination where a SNF has been out of substantial compliance for more than six months with one or more of the Medicare participation requirements identified by a survey as unmet or fails to submit an acceptable plan of correction within a specified timeframe. These provisions also permit termination at any time where, based on a survey, a SNF is found not to be in substantial compliance with one or more participation requirements, whether or not CMS has determined that the noncompliance poses immediate jeopardy. The August 8, 2013 survey found Blossom South out of substantial compliance with multiple participation requirements; thus, CMS had clear legal authority to terminate under these provisions, which CMS cited in the termination letter as the legal basis for the termination.[7]

In addition to arguing that CMS's termination letter notified it that the legal basis for the termination was its alleged failure to graduate from the SFF program, Blossom South argues that the termination letter "failed to duly notify [Blossom South] that the termination was based on any deficiency other than" the three level "F" and "G" deficiencies identified in that letter. RR at 15. Accordingly, Blossom South contends, "CMS should not be allowed to terminate based upon failure to be in substantial compliance with any other deficiencies[.]" *Id.* In support of its argument, Blossom South cites both 42 C.F.R. § 488.402(f), providing in pertinent part that when CMS

[7] Despite the use of the word "mandated" in the letter, Blossom South should have known from the statute and regulations cited that CMS also had a discretionary basis for the termination. *See, e.g., Oak Lawn Pavilion, Inc.*, DAB No. 1638, at 9 (1997)("any long-term care facility certified under Medicare is presumed to be on notice of program requirements through the applicable regulations").

chooses to apply one or more remedies, CMS "gives the provider notice of the remedy, including the—(i) Nature of the noncompliance . . . ," and 42 C.F.R. § 489.53(d)(4), providing in pertinent part that the notice of termination "states the reasons for…the termination[.]"

We note that while CMS pointed out in the termination letter that because the noncompliance with the three specifically listed participation requirements was at a scope and severity level greater than "E," Blossom South was not eligible to graduate from the SFF program, CMS did not state that the termination was based only on noncompliance with these requirements. Moreover, CMS referred generally to the August 8, 2013 survey, and all of the deficiencies cited at the noncompliance level are described in the SOD for that survey, a copy of which Blossom South acknowledges receiving.[8]

In any event, we agree with the ALJ's finding that Blossom South "was not misled by CMS's notice letters; its hearing request leaves no doubt that it well understood that the issue before me would be whether it was in substantial compliance." ALJ Decision at 7. There is no indication in the hearing request that Blossom South was contesting only the three level "F" and "G" deficiencies specified in the termination letter. Instead, the hearing request states in part that Blossom South "contests the issuance of **all** the deficiencies cited by the [state survey agency] and CMS including, but not limited to any deficiency in the category of quality of care" as well as "**each** and **all** of the findings of fact for **each** and every F-tag that the [state survey agency] seeks to cite, as well as **all** of the conclusions that the findings constituted violations of **each** Tag number." Hearing request dated 8/20/13, at 2 (emphasis in original). Thus, the hearing request clearly contests all of the noncompliance identified by the survey.[9]

Even if Blossom South did not understand from the termination letter that CMS was relying on all of the noncompliance identified by the survey, there is no dispute that CMS's prehearing brief, dated September 20, 2013, addressed all such noncompliance. As Blossom South recognizes (RR at 13), after an administrative appeal has commenced, a federal agency may assert and rely on new or alternative grounds for the challenged action or determination as long as the non-federal party has notice of and a reasonable

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[8] Blossom South also cites *Beverly Health & Rehab. Servs. v. Thompson*, 223 F.Supp.2d 73, 113 (D.D.C. 2002), in support of its position. RR at 15. However, the court there rejected the facility's argument that it did not receive fair notice that the termination was based on all the deficiency findings, not just the immediate jeopardy findings, where the termination notice stated in part that the "survey found that your facility was not in substantial compliance with participation requirements and that conditions in your facility constituted immediate jeopardy to resident health or safety." Blossom South does not explain how *Beverly* helps rather than hurts its own case.

[9] Blossom South asserts that this language merely indicates it "was aware" of all the deficiencies cited and that another part of its request "specifically challenged the deficiencies cited in CMS's termination letter, which was limited to F309, F333 and F371." Blossom South Reply Br. (Reply) at 4-5. Since we have already rejected Blossom South's argument that the termination letter limited the basis for the termination to the noncompliance with those three participation requirements, we need not address this assertion further.

opportunity to respond to the asserted new grounds during the administrative proceeding." *Union Hospital, Inc.*, DAB No. 2463, at 7 (2012), citing *Green Hills Enterprises, LLC*, DAB No. 2199, at 8 (2008). If Blossom South viewed CMS's prehearing brief as raising issues not encompassed by the termination letter, Blossom South could have asked the ALJ for more time to address those issues before the hearing commenced. It did not do so.[10]

Accordingly, we conclude that Blossom South had timely and adequate notice that the termination was based on Blossom South's noncompliance with all of the Medicare participation requirements cited in the SOD for the August 8, 2013 survey at a scope and severity level of "D" or higher.

B. CMS was authorized to terminate Blossom South's Medicare participation based on all of the noncompliance found on the August 8, 2013 survey.

1. The ALJ's conclusion that CMS was authorized to terminate Blossom South's Medicare participation based on any of the eight undisputed deficiencies identified by the survey is free of legal error.

In FFCL A, the ALJ concluded that Blossom South was not in substantial compliance with eight participation requirements relating to level "D" and level "E" deficiencies identified by the August 8, 2013 survey and that CMS "may terminate its program participation based on any one of those deficiencies alone." ALJ Decision at 5. In the discussion following this FFCL, the ALJ stated that any one of these deficiencies establishes Blossom South's noncompliance, and that Blossom South had not addressed any of them in its submissions. The ALJ concluded, "The unrebutted evidence thus establishes that the facility was not in substantial compliance, and CMS was therefore authorized to impose a remedy, including termination." *Id*. at 5-6. The ALJ then set out the evidence relating to each of the eight deficiencies that she found established Blossom South's noncompliance based on those deficiencies. ALJ Decision at 8-19.

[10] Blossom South had previously requested a delay for filing the parties' simultaneous prehearing briefs and in the September 25, 2013 hearing date due to religious holidays in September. The ALJ denied the request, noting that Blossom South itself had requested an expedited hearing without mentioning the religious holidays and stating that she "cannot guarantee" when she would be able to schedule a hearing after October 1 due to the lack of a federal budget. Ruling dated 9/16/13; *see also* ALJ Decision at 3-4 n.2. Blossom South now suggests that because of the ALJ's procedural rulings, and particularly the requirement for simultaneous briefs, it "was not adequately apprised that CMS now had additional grounds . . . to terminate" Blossom South. RR at 4. However, Blossom South never asserted that it needed an opportunity to address the alleged "additional grounds" and has made no showing of prejudicial error in the ALJ's ruling.

Blossom South's request for review by the Board states generally that Blossom South "is challenging each and every finding of fact and law made by the ALJ with respect to the termination of [Blossom South]'s participation in the Medicare program by" CMS. RR at 1. However, Blossom South does not specifically dispute any of the individual findings concerning the eight participation requirements in question or the ALJ's conclusion that the unrebutted evidence establishes that Blossom South was not in substantial compliance with these requirements. Nor does Blossom South argue that the Board should remand the case to the ALJ to permit Blossom South to present evidence of its compliance with any of these participation requirements if the Board rejects its argument that it lacked timely notice of the basis for the termination. Finally, Blossom South does not deny that if it received such notice (which we have concluded it did), CMS was authorized to terminate its Medicare participation on the ground that it was not in substantial compliance with one or more of the eight participation requirements in question.

Accordingly, we uphold FFCL A without further discussion. Moreover, as we discuss below, Blossom South has not provided a basis for reversing the ALJ's determination of noncompliance with respect to the three remaining participation requirements. Thus, there is a sufficient basis for upholding the termination even assuming Blossom South could prevail on its notice argument.

2. The ALJ's conclusion that Blossom South was not in substantial compliance with 42 C.F.R. § 483.25 is supported by substantial evidence and free of legal error.

In FFCL B, the ALJ concluded that Blossom South was not in substantial compliance with section 483.25 ("Quality of Care"), which contains the overarching requirement that –

> [e]ach resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.

The ALJ relied on findings regarding Resident 6 (also referred to as R6), an 81-year-old man who was admitted to the facility on December 27, 2012 with diagnoses including dysphasia (difficulty swallowing) and cancer of the larynx. ALJ Decision at 19; CMS Ex. 1, at 13. An April 1, 2013 Minimum Data Set Assessment of the resident's "Oral/Dental Status" showed that Resident 6 had "Mouth or facial pain, discomfort or difficulty with chewing." CMS Ex. 1, at 14; P. Ex. B at 12. The resident's comprehensive care plan, initially dated January 16, 2013 and still in effect on July 4, 2013, identified dental care as a problem and stated in a column headed "Goal" that "Resident will have oral hygiene performed every day." CMS Ex. 1, at 14; P. Ex. B at 57. The care plan also directed staff to "Monitor for loose, missing, or carious teeth,

poorly fitting or broken dentures," "Monitor mouth, tongue, and gums for…sores…," and "Arrange for Dental consult yearly and as needed." P. Ex. B at 57. The resident, who had upper and lower partial dentures (P. Ex. A at 1), told the surveyor on July 18, 2013 that "he has mouth/facial pain with no relief from his dental bridge and the wires of the front tooth and that his teeth hurt." CMS Ex. 1, at 15. On July 23, 2013, Resident 6 was evaluated for oral pain by a nurse practitioner, who "reported that the resident had oral/gum pain, especially when his partial plate [dentures] was in, because the metal rubbed on his gums" and "described several 'ulcerated' areas on the upper and lower gums." ALJ Decision at 21; *see also* P. Ex. B at 30. The nurse practitioner also observed "several rotted and partial teeth, as well as 'pockets' where teeth used to be." *Id.* The nurse practitioner's progress notes list several measures to address these problems, including chlorhexidine oral rinse every four hours, Orajel every eight hours, keeping the partial dentures out, a dietary consult for soft foods, pain control, and a dental consult for tooth extractions. P. Ex. B at 30.

The ALJ observed that the record contains minimal progress notes for Resident 6 prior to July 18 but that "some notes record the resident's occasional complaints of tooth and mouth discomfort." In particular, the ALJ noted that the resident asked to be evaluated for softer foods on March 11, and complained on March 13 and again on March 14 that a broken tooth was bothering him, indicating on the latter occasion that he had had pain in his lower jaw but currently had no pain. ALJ Decision at 20, citing P. Ex. B at 14, 16. The ALJ also stated that she saw "no evidence that staff monitored R6's mouth and teeth on a regular basis—much less daily." *Id*. at 19-20; *see also id*. at 20 ("no evidence shows any monitoring or follow-up until after July 18, when he happened to end up in the survey sample"). Thus, the ALJ stated, Blossom South "well knew that the resident's teeth would and did cause him pain—if not constantly, at least sporadically – and limitations." *Id*. at 22 (footnote omitted). The ALJ continued:

> R6 was not able to eat normal food and experienced sporadic pain, all because of the sorry state of his mouth. Yet, the facility provided minimal monitoring and services. [footnote omitted] It was therefore not providing the "necessary care and services to allow [him] to attain . . . the highest practicable physical, mental, and psychosocial well-being," and was not in substantial compliance with 42 C.F.R. § 483.25.

Id.

On appeal, Blossom South disputes the ALJ's conclusion that it was not in substantial compliance with section 483.25, arguing that the "ALJ erred in finding that R6's condition deteriorated because the Facility failed to check his teeth and gums." RR at 28. Blossom South asserts that Resident 6's care plan "was followed during the entirety of [his] stay" since "nursing staff monitored [his] conditions and the nurse practitioner personally monitored R6 two to three times per week." RR at 28; *see also* RR at 29. In

addition, Blossom South asserts that after an initial comprehensive dental examination on January 17, 2013 by McClure Dental Services, P.C., it "constantly monitored R6's oral condition and documented [his] repeated denials of oral pain" and "attended to all of [his] oral pain complaints by scheduling and arranging consultations with" that dental office. RR at 28. Blossom South states that "[i]n all subsequent examinations, McClure Dental Services, P.C. noted that R6's condition had not deteriorated and maintained the same recommendations" for the extraction of 11 teeth and roots allegedly made by the dentist at the time of the initial examination and declined by the resident. *Id*.

Blossom South's arguments have no merit. Although Blossom South asserts that it followed its care plan for Resident 6's dental care, Blossom South does not specifically allege that Resident 6 had oral hygiene every day, as required by the care plan, much less cite any evidence to show that this was the case. Moreover, the nurse practitioner testified only that "[t]ypically, I see Resident #6 two to three times per week," not that she currently or previously monitored Resident 6's oral condition on such occasions. P. Ex. 4, at 3. In addition, the progress notes Blossom South cites as evidence of monitoring show only that its nursing staff questioned Resident 6 about oral pain on three occasions after he complained to nursing staff on March 13, 2013 that a broken lower tooth was bothering him. P. Ex. B at 14-15 (interdisciplinary progress notes indicating that resident denies "tooth pain" on March 14, 20, and 28), cited at RR at 28.[11] Neither these sporadic reactions by staff to the resident's complaints nor the fact that the resident "was seen at Dr. M[.]'s office for broken teeth and other dental hygiene issues" on March 2 and 21 (P. Ex. 4, at 3) is evidence of compliance with the care plan's specific requirements that staff provide oral hygiene every day and monitor Resident 6 for loose, missing, or carious teeth, for poorly fitting or broken dentures, and for sores.

The Board has consistently held that where a facility in its policies or care plans requires that specific measures be taken in caring for residents, those measures are evidence of the facility's evaluation of what must be done to attain or maintain a resident's "highest practicable physical, mental, and psychosocial well-being" as required by the overarching introductory language to section 483.25. *See, e.g., Azalea Court*, DAB No. 2352, at 9 (2010) (citing cases), *aff'd, Azalea Court v. U.S. Dep't of Health & Human Servs.*, 482 F. App 'x 460 (11th Cir. 2012). Here, Blossom South developed a care plan for Resident 6 that required daily oral hygiene and monitoring multiple aspects of his oral condition. Given the evidence about the status of R6's teeth and gums from the survey and the nurse practitioner's notes, the ALJ could reasonably conclude that Blossom South's staff did not monitor Resident 6's oral condition or provide him with daily oral hygiene as required by the care plan in the absence of any progress notes or other facility records or evidence showing such monitoring.

[11] Blossom South also cites a progress note in a Monthly Medical History, Physical and Plan of Care stating that the resident denies dental pain, but that document is dated August 29, 2013, after the date of the survey. P. Ex. B at 36-37.

Blossom South argues that CMS's finding of noncompliance is not justified because the facts in the record "generally support the assertion that R6 was receiving the best possible care from [Blossom South] under the circumstances and only experiencing discomfort from his pre-existing injuries." Reply at 13. In particular, Blossom South asserts that the "ulcerated" areas on the resident's gums observed by the nurse practitioner who examined him after the survey were an inflammation due to carious roots that Resident 6 had declined to have extracted, and not ulcerations caused by ill-fitting dentures, as the ALJ found. RR at 29. According to Blossom South, given Resident 6's "pre-existing conditions and diagnoses," Blossom South "cannot be required to ensure a positive outcome in R6's overall health." Reply at 13; *see also* RR at 28-29 ("oral pain was unavoidable" and "the likelihood of an improvement in his oral condition was slim" given his "age and prognosis," "significant oral problems, including carious roots, upon admission," and unwillingness to have teeth extracted).

The actual cause of Resident 6's oral pain is irrelevant, however. As noted above, the care plan for Resident 6 included a directive to monitor him for "poorly fitting or broken dentures." This shows that Blossom South recognized that if the resident's dentures were poorly fitting or broken, they could cause him problems. Even if the dentures turned out not to be the source of the oral pain Resident 6 reported to the surveyor (and at times to nursing staff), that did not excuse Blossom South's failure to provide a type of care it had identified as necessary to meet the resident's assessed needs.

Even if Resident 6's oral pain was caused by "carious roots," there is no support in the record for Blossom South's assertion that the resident contributed to his continued pain by declining a recommendation by the dentist, at the initial dental examination scheduled by Blossom South, for extraction of the affected teeth. RR at 28, citing P. Ex. A at 1 (report of initial dental examination); P. Ex. 1 (declaration of C.M., D.D.S.) at 1, 3. The ALJ found that the dentist on whose testimony Blossom South relies "does not say when or by whom the recommendation [for extraction] was made," and that "the dental records, which [the dentist] characterizes as 'accurate,' show that the issue of extraction was raised for the first time on July 29, *after* [the surveyor] identified R6 as suffering mouth and facial pain." ALJ Decision at 21 (italics in original). In particular, the ALJ found that the written reports of the resident's dental examinations on January 17, March 2, and March 21 contained no recommendation for any extraction and that all of these reports "describe the resident as 'cooperative' and 'desirous' of care." *Id*., citing P. Ex. A at 1, 3, 5. Blossom South does not point to any error in the ALJ's findings.

Blossom South also suggests that it was excused from monitoring Resident 6's dental status absent any complaints of oral pain. Blossom South points to a report prepared on July 18, 2013 that it said indicated "that Resident 6 had no complaints of pain over the past month except for intermittent left hip pain." Reply at 12, citing P. Ex. B at 45. Nothing in the care plan for Resident 6 indicates that his dental status was to be monitored only if he complained of oral pain. Moreover, Blossom South does not

explain how the report would excuse Blossom South's failure to monitor Resident 6's dental status before July 18. Blossom South knew Resident 6 was experiencing oral pain at least as of April 1, 2013, when it assessed him as having "[m]outh or facial pain, discomfort or difficulty with chewing" (CMS Ex. 1, at 14; P. Ex. B at 12).

For the foregoing reasons, we uphold the ALJ's conclusion that Blossom South was not in substantial compliance with section 483.25.

3. The ALJ's conclusion that Blossom South was not in substantial compliance with 42 C.F.R. § 483.25(m)(2) is supported by substantial evidence and free of legal error.

In FFCL C, the ALJ concluded that Blossom South was not in substantial compliance with the part of section 483.25(m) ("Medication Errors") providing that "[t]he facility must ensure that—. . .(2) Residents are free of any significant medication errors." The ALJ relied on findings regarding two of the residents for whom the SOD described medication errors. *See* CMS Ex. 1, at 27. We discuss the two residents in turn below. However, we conclude that the evidence regarding either resident, by itself, is sufficient to establish that Blossom South failed to comply substantially with section 483.25(m)(2).

(a) Resident 27

Resident 27 (also referred to as R27) was a terminally ill resident who was suffering significant pain and receiving comfort measures only. ALJ Decision at 23. A March 3, 2013 nurse practitioner's telephone order recorded by a facility nurse discontinued a February 24 order for morphine intramuscularly (IM) as needed and gave a new order for 3 mg morphine IM every 4 hours for pain. "Unidentified staff" altered the amount of morphine on the document recording the March 3 telephone order by writing the numeral "4" over the numeral "3" in front of "mg." ALJ Decision at 23; *see also* CMS Ex. 13, at 1-2, 17-18; CMS Ex. 1, at 28-29. The same alteration appears on the medication administration record (MAR) for Resident 27 for the month of March.[12] ALJ Decision at 23; CMS Ex. 13, at 23. The MAR shows the order for each of the resident's medications and includes a grid of dates and times that was initialed by a nurse each time a medication was administered. CMS Ex. 13, at 23. According to Blossom South's chief operating officer, "[n]urses are required to consult the MAR for the correct dose and order." P. Ex. 3 (declaration of F.I., R.N.) at 5. After describing the alterations on the MAR and on the record of the telephone order, the ALJ stated: "Thus, it seems, the facility records are completely unreliable, and the facility cannot establish that R27 was free of significant medication errors. As CMS correctly notes, the facility has no idea

[12] Although not mentioned by the ALJ, the March 3 order also authorized additional morphine IM "PRN" (as needed) for pain, and both the amount and frequency were written over. CMS Ex. 13, at 1, 18; CMS Ex. 1, at 28.

how much morphine R27 received." ALJ Decision at 23. Addressing Blossom South's argument that "CMS has not established that R27, in fact, received an incorrect dose," the ALJ further stated: "Petitioner has the burdens here upside-down. The *facility* must ensure that medications are administered as ordered. A facility cannot avoid this responsibility by presenting records that make it impossible to verify the amount of the drug actually administered. Where…drug records are falsified, the facility has obviously failed in its responsibility." *Id*. at 24 (italics in original).[13]

Although it acknowledges that the MAR for March 2013 was altered by a staff member to show a morphine dosage not prescribed by Resident 27's physician, Blossom South argues that this alteration does not establish that there was a medication error since "there is sufficient evidence in the record to show that R27 received the *correct dosage*" of morphine IM during that month.[14] RR at 21 (italics in original). Blossom South points to "Nurse's Medication Notes" documenting that on March 23, the resident "refused an administration of '0.6 ml (3mg)' of morphine sulfate,"[15] and that on March 30 and 31, the resident "refused '0.6 ml' of morphine." *Id*., citing P. Ex. C at 8.[16] Blossom South also says that on March 31, "a nurse documented an administration of '3mg'morphine in R27's interdisciplinary progress notes." *Id*. at 21-22; *see also* P. Ex. C at 39. According to Blossom South, "[t]hese entries clearly indicate that the Facility's nurses knew and administered the correct dose of morphine sulfate to R27." RR at 22. Blossom South

[13] The last sentence reads in full, "Where water is substituted for drugs and drug records are falsified, the facility has obviously failed in its responsibility." In finding that water was substituted for drugs, the ALJ relied on an investigation of narcotics violations by the New York State Bureau of Narcotics Enforcement conducted at the same time as the survey that "found that the temper [sic] resistant caps had been removed on *sixteen* vials of morphine and the vials had been filled with water[.]" ALJ Decision at 23 (italics in original). The ALJ stated, "If facility staff (or others) are substituting water for a powerful narcotic that was designated for its residents, the facility is not ensuring that the resident is receiving any of that ordered medication." *Id*. Blossom South asserts that this is a "red herring" because there is "no evidence linking any of the tampered vials of morphine to [Resident 27] or any other residents cited" in the SOD, which "is devoid of any reference to this investigation[.]" Reply at 14. We need not address this issue as we conclude that the other evidence on which the ALJ relied constitutes substantial evidence of a significant medication error with respect to Resident 27.

[14] Blossom South argues that "the ALJ incorrectly found that [Blossom South] should be held accountable for the criminal actions of an employee who altered R27's medication records." RR at 23. The ALJ did not refer to the employee actions as "criminal" but properly held, consistent with settled Board precedent, that a "facility 'cannot disown the consequences' of inadequate care by the simple expedient of pointing the finger at staff, who are the agents of the facility." ALJ Decision at 24 (citations omitted).

[15] For purposes of this decision, we assume that "morphine sulfate" refers to the morphine IM that was prescribed for Resident 27 since Blossom South does not indicate that there is any distinction.

[16] We assume for purposes of this decision that the entry for March 23 refers to 3 mg although it is difficult to decipher. The entries for March 30 and 31 actually appear on the following page, P. Ex. C at 9.

also suggests that staff administering the morphine were not misled by the alterations because the MAR "clearly shows that the correct[] prescription strength of morphine sulfate was 3mg" even though someone "boldly" wrote "the number 4 over the number 3[.]"[17] Reply at 14.

Contrary to what Blossom South implies, the ALJ did not find that there was necessarily a medication error just because the amount of morphine IM ordered for Resident 27 on March 3 was altered on the MAR. Instead, the ALJ reasoned that there was a medication error because 1) it was unclear from both the record of the telephone order and the MAR for March 2013 what amount of morphine IM had been ordered for Resident 27 and 2) Blossom South did not show that its staff in fact gave (or offered) her the correct amount that month. Moreover, substantial evidence in the record supports the ALJ's finding that Blossom South did not make that showing. The entries in the Nurse's Medication Notes that Blossom South cites pertain to only four of the multiple doses that should have been administered (or offered) from March 4 through 31 on a schedule of every four hours. The ALJ could reasonably determine that these four entries are not sufficient to support an inference that all of the 168 doses in question (6 per day for 28 days) were for the correct amount. Moreover, Blossom South does not explain how staff would have known that the dosage actually prescribed was 3 mg despite the fact that the numeral "4" was written over the numeral "3" on the MAR and why staff could not have instead concluded that the numeral "4" corrected an error by recording an actual prescription for 4 mg.[18]

The ALJ also noted that documents titled "Controlled Medication Utilization Record," which she referred to as "Narcotic Utilization Sheets," for Resident 27 "show that staff administered the wrong amount of morphine on numerous occasions." ALJ Decision at 23 n.16. The ALJ found that these records "document 22 instances in which 4 mg . . . were administered and 21 instances in which 5 mg. . . were administered." *Id*., citing CMS Ex. 13, at 43-47. All 22 of the entries showing a dose of 4 mg and six of the 21 entries showing a dose of 5 mg are for March 7-12, the only dates in March 2013 shown on these records. CMS Ex. 13, at 43-44. The ALJ could reasonably view these sheets as evidence that, of the 168 doses of morphine IM Resident 27 should have been given in March 2013, at least 28 doses were for an amount that exceeded the 3 mg actually prescribed by 1-2 mg. Blossom South argues that the "narcotics utilization sheet merely

[17] While Blossom South states that "overwhelming evidence in the record indicates that the alterations did not occur in March, 2013," it cites no evidence to support this assertion and then totally undercuts it with the admission that "it is unclear precisely when such alterations were made." Reply at 14 n.4. Absent any evidence to the contrary, the ALJ could reasonably infer that the alterations existed during the period relevant to her findings.

[18] Blossom South also argues that the "ALJ's ruling with respect to burden of proof is clearly erroneous and contrary to controlling precedent" that "CMS must set forth a *prima facie* case that a facility is not in substantial compliance." RR at 20 n.8. However, CMS here made a prima facie case by showing that Blossom South's own records made it impossible to determine whether its staff had administered medication as ordered.

keeps track of medication quantities and the nurses who administer such narcotics" and that the sheet is "not probative in determining the amount of medication administered." Reply at 15 n.5, citing P. Ex. 3 (declaration of F.I., R.N.) at 5. However, this argument is undercut by the fact that the sheets in question here have a "Dose Given" column filled out with the amounts identified by the ALJ. F.I.'s testimony that the "sheet is for the sole purpose of keeping track of narcotics quantities and accountability for particular nurses who administer narcotics" (P. Ex. 3, at 5) is inconsistent with the sheets in question here and the entries thereon. In addition, F.I.'s statement that the "sheet is filled out after the medication is administered" (P. Ex. 3, at 5) undercuts Blossom South's suggestion that the amounts in the "Dose Given" column reflect the amounts removed from the facility's supply of the drug rather than the doses actually given. F.I. also stated that the sheet "is not a reliable source for a nurse to determine the appropriate dose to give a patient." P. Ex. 3, at 5 (emphasis added). However, this statement does not address the issue here of whether the sheet is a reliable basis for determining the dose actually given.

Blossom South also asserts that the ALJ failed to consider whether the alleged medication errors were "significant" within the meaning of section 483.25(m)(2) and that "CMS did not satisfy its burden of proof on this issue." RR at 22-23. Blossom South argues that the surveyor's opinion that the alleged medication errors were significant "was refuted by the more probative testimony of" Blossom South's physician expert. RR at 23, citing P. Ex. 2 (declaration of N.J., M.D.). Blossom South argues that the surveyor's testimony "falls short of the required analysis to prove a significant medication error" because it "fails to consider R27's specific condition and the frequency of the error" and instead "merely restates boilerplate side effects of morphine sulfate[.]" RR at 22; Reply at 15. Blossom South argues that, in contrast, Dr. N.J. "performed the required analysis in determining whether such an alleged medication error was significant." RR at 22.

The preamble to the rulemaking adopting section 483.25(m)(2) identifies three factors to guide a surveyor in judging whether a medication error is significant: (1) Drug category; (2) Resident condition; and (3) Frequency of error. 56 Fed. Reg. 48,826, 48,853 (Sept. 26, 1991). These criteria are set forth in CMS's interpretive guidelines for section 483.25(m)(2), to which Blossom South cites. RR at 20, citing SOM, App. PP (tag F333) (available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf). The SOM also states that a significant medication error is one that "causes the resident discomfort or jeopardizes his or her health and safety." SOM, App. PP (tag F333). Noting this statement, the Board has held that actual harm is not a prerequisite for concluding that a medication error was significant. *See Life Care Ctr. of Elizabethton*, DAB No. 2367, at 7 (2011), citing *Life Care of Tullahoma*, DAB No. 2304, at 44 (2010).

The surveyor's testimony specifically identified Resident 27's numerous respiratory, cardiovascular, and central nervous system diagnoses and the potential adverse reactions for each of these diagnosis categories. CMS Ex. 19 (declaration of Surveyor H.M., R.N.) at 6-7. The surveyor relied on the 2013 Nursing Drug Handbook to identify these potential adverse reactions. *Id*. Contrary to what Blossom South argues, the surveyor identified several of the resident's diagnoses and the potential adverse reactions associated with each of them. In addition, the surveyor stated that "the documentation did not clearly show how much medication was being given to Resident #27" and noted that the narcotics utilization sheets "that could be found by the facility" showed that the resident received a dose of morphine IM in excess of 3 mg more than 40 times.[19] CMS Ex. 19, at 5. The surveyor (and the ALJ) could reasonably conclude from these facts that the medication error jeopardized Resident 27's health and safety because there was a risk that the amount of morphine she received could cause her to suffer one or more of the potential adverse reactions described in the Nursing Drug Handbook for her particular medical conditions. *See* *http://www.merriam-webster.com/dictionary*, defining "jeopardize" as "to expose to danger or risk."

Dr. N.J. also testified about morphine and its potential adverse side effects, stating that morphine is a narcotic pain reliever; that ingesting it at a dosage higher than prescribed can cause a morphine overdose; and that the potential side effects of a morphine overdose include respiratory distress, lethargy, dizziness, hypotension, confusion, drowsiness, and in cases of extreme overdoses, death. P. Ex. 2, at 3. However, Dr. N.J. concluded that, even assuming Resident 27 received 4 mg of morphine IM instead of the prescribed 3 mg "on several occasions during March 2013" as found by the surveyors, "it is my opinion to a reasonable degree of medical certainty that the alleged medication error . . . did not have the potential to cause harm or discomfort" to Resident 27. *Id*. at 3-4. His conclusion, he indicated, took into consideration "the facts, circumstances and medical history of Resident #27." *Id*. at 4. He also stated that Resident 27 "most likely developed a physiological tolerance to morphine since she had been receiving morphine on a daily basis for over a month" and that 8.5 mg was "a tolerable dose" based on her weight. *Id*.

The ALJ indicated that she did not accord much credibility or weight to Dr. N.J.'s testimony by stating that his testimony "downplays the significance of . . . the very disturbing irregularities surrounding R27's drugs[.]" ALJ Decision at 25. In general, the Board defers to ALJ findings on the weight and credibility of witness testimony absent a compelling reason to do otherwise. *See, e.g., Woodland Oaks Healthcare Facility*, DAB No. 2355, at 7 (2010). For the reasons explained below, we find no compelling reason not to defer to the ALJ in this instance.

[19] The figure given by the surveyor appears to include dates in April as well as March. *See* CMS Ex. 13, at 43-47.

Dr. N.J.'s testimony about the potential adverse effects of ingesting morphine in excess of the prescribed dosage is essentially consistent with the surveyor's testimony on that issue. Dr. N.J.'s conclusion addresses only the likelihood that the medication error would cause Resident 27 discomfort or harm and relies, in part, on the fact that nursing notes apparently did not mention that she suffered any adverse side effects. However, even if adverse side effects were unlikely, that does not mean the potential for such side effects did not exist. As already noted, the potential for adverse side effects indicates that the medication error was significant.

In addition, Dr. N.J.'s opinion was predicated on the unwarranted assumption that Resident 27 received 4 mg of morphine IM every four hours instead of 3 mg as ordered. *Id*. The fact that someone changed the MAR to show 4 mg of morphine IM every four hours instead of 3 mg as ordered does not necessarily mean that Resident 27 received only an additional 1 mg of morphine IM every four hours. As the ALJ found, the record of the telephone order and the MAR were altered so that it was not clear from that evidence what dose the physician ordered; accordingly, the amount of morphine IM staff gave to Resident 27 in March 2013 is unknown except for the 28 doses of 4 or 5 mg shown on the narcotic utilization sheets. Moreover, Dr. N.J. did not take into account that Resident 27 had an order for morphine IM PRN (which was also altered on the MAR) in addition to the order for 3 mg morphine IM every four hours. Thus, the amount of morphine IM Resident 27 received within a four-hour period could have totaled more than 4 mg.

Moreover, although Dr. N.J. stated that he considered "the facts, circumstances and medical history of Resident #27," he did not explain how any of the resident's specific medical diagnoses helped form the basis for his opinion. Likewise, in stating that up to 8.5 mg would be a "tolerable dose" of morphine for Resident 27, he did not explain what he meant by "tolerable dose" and relied only on her weight and on his opinion that she would have developed a "physiological tolerance" to morphine after receiving it daily for one month. It is not clear that Dr. N.J.'s conclusion that 8.5 mg was a "tolerable dose" for Resident 27 included consideration of how her specific medical diagnoses might affect her reaction to the drug.

For these reasons, we conclude that substantial evidence supports the ALJ's conclusion that the medication error with respect to Resident 27 was significant and constituted noncompliance with section 483.25(m)(2).

(b) Resident 89

Resident 89, who had a history of stroke, venous insufficiency, and bipolar disorder, had a physician's order, dated June 2, 2013 for morphine IR (instant release) every 12 hours as needed.[20] ALJ Decision at 18, 24; CMS Ex. 8, at 2, 4. A nursing progress note as well as a narcotic utilization sheet showed that morphine IR was administered to Resident 89 twice on July 8, 2013, at 3:00 a.m. and 7:00 a.m., for complaints of left-sided pain.[21] ALJ Decision at 18, 24; CMS Ex. 8, at 1, 5. A nurse practitioner told the surveyor that, to justify giving a second dose of morphine so soon after administering the first dose, the LPN on duty would be expected to call for a telephone order and would be required to record the order. ALJ Decision at 18; CMS Ex. 1, at 49. The nurse manager told the surveyor that she had been unable to find a telephone order. ALJ Decision at 19; CMS Ex. 1, at 49. A nurse's note dated July 8 at 7:20 a.m. states "NP [nurse practitioner] notified about Resident's pain. Acute sheet done for evaluation." P. Ex. G at 7. Nurse Practitioner M.S. testified that she spoke to the facility nurse by telephone at approximately 6:00 a.m. and "gave the nurse permission to administer a dose of Morphine Sulfate Immediate Release 15mg, even though the previous dose was given at 3:00 a.m."[22] P. Ex. 4 (declaration of Nurse Practitioner M.S.) at 9. She further testified that the 7 a.m. dose "was not a medication error because I orally authorized the administration of this dose." *Id*.

The ALJ did not accept the testimony of the nurse practitioner that she ordered the dose of morphine IR given at 7:00 a.m. on the grounds that Blossom South produced no record of a telephone order for that dose, the nurse practitioner produced no written record showing that she ordered it, and the contemporaneous nurse's note established only that the nurse practitioner was notified about the resident's pain. ALJ Decision at 24-25. The ALJ concluded that giving an additional dose of morphine IR to Resident 89 without an order was a significant medication error, stating: "The possible dangers associated with administering too much instant release morphine," including bradycardia, cardiac arrest, shock, hypertension, hypotension, tachycardia, apnea, respiratory arrest, and respiratory depression, "are documented on the product label and in standard nursing and pharmaceutical texts." *Id*. at 25, citing CMS Ex. 20 (declaration of Surveyor L.W.) at 5-6, and 2013 Nursing Drug Handbook. The ALJ stated that these side effects "could be particularly troublesome for someone like R89, who has a history of cardiac problems as well as stroke." *Id*. at 25.

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[20] The ALJ noted, but did not otherwise address, that Resident 89 also received 15 mg morphine sulfate, extended release (ER), twice a day. ALJ Decision at 24 n.17, citing CMS Ex. 8, at 2.

[21] It is undisputed that she received the two doses although the MAR showed only the 3:00 a.m. dose. CMS Ex. 8, at 3.

[22] The record does not show whether this was the same nurse practitioner who spoke to the surveyor.

Blossom South argues that the ALJ "unduly discredited the nurse practitioner's uncontradicted testimony" that she ordered the second dose of morphine IR. RR at 24; *see also* Reply at 15-16. However, Blossom South does not dispute the ALJ's finding that a signed, written order for a narcotic such as morphine is required by law. ALJ Decision at 25; Tr. at 65, 107-108. In light of this requirement, the ALJ could reasonably conclude from the absence of any documentary evidence of an order that no order was given.

Blossom South also argues that the ALJ erred in accepting the opinion of Surveyor L.W. that the administration of the second dose of morphine IR to Resident 89 was a significant medication error. RR at 18-19. Surveyor L.W. was a registered dietician. CMS Ex. 20, at 1. Blossom South asserts that Surveyor L.W. was therefore "unqualified to opine on the effects of a narcotic substance on a resident." RR at 18. Blossom South also argues that Surveyor L.W.'s testimony regarding the dangers of morphine "was a mere restatement of symptoms from a nursing drug handbook without taking into consideration the required particularities of the patient's condition and the nature of the error." *Id*. at 19.

Blossom South's arguments lack merit. According to her curriculum vitae, Surveyor L.W. had been a member of a survey team for nearly six years and performed annual surveys for 68 nursing homes as well as approximately 450 abbreviated surveys. CMS Ex. 20, Att. A at 1. She also testified that she had received training and was certified as a surveyor. Tr. at 100-101. Thus, the ALJ could reasonably determine that she was qualified based on her training and experience as a surveyor to give an opinion about the effect of giving Resident 89 more morphine than was ordered.[23]

Moreover, the surveyor's testimony specifically identified Resident 89's numerous cardiovascular, respiratory, and central nervous system diagnoses and the potential adverse reactions for each of these diagnosis categories. CMS Ex. 20, at 5-6. The surveyor also noted that Resident 89 received two 15 mg doses of morphine IR only four hours apart instead of every 12 hours as needed as ordered by the physician. *Id*. at 4. The surveyor (and the ALJ) could reasonably conclude that Resident 89's receiving twice the amount of morphine ordered within only a few hours put the resident at risk of

[23] Surveyor L.W. also testified that, at the time of the survey, she consulted with other members of the survey team, which included nurses and pharmacists, who "reaffirmed" her opinion that the medication error was significant. Tr. at 64. Citing this testimony, Blossom South argues that Surveyor L.W.'s "opinion was not even her own, but that of an undisclosed team of surveyors" and that it "is impermissible hearsay[.]" RR at 19. Blossom South's argument ignores the fact that an SOD finding "constitutes not the opinion of an individual surveyor, but 'the collective determination by the . . . survey team that the facts reported evidenced a deficiency[.]'" *Omni Manor Nursing Home*, DAB No. 1920, at 11 (2004), quoting *Beechwood Sanitarium*, DAB No. 1906, at 41 (2004) *aff'd, Beechwood v. Thompson*, 494 F.Supp.2d 181 (W.D.N.Y. July 26, 2007); *see also Golden Living Ctr.-Foley*, DAB No. 2510, at 27 (2013) ("ALJ could reasonably credit the surveyor's testimony about the team's collective opinion about the applicable standard of care.").

suffering any of the potential adverse reactions described in the Nursing Drug Handbook for her particular medical conditions. In addition, as the ALJ noted, Blossom South proffered no testimony on the issue of whether the medication error with respect to Resident 89 was significant, whereas it had put on evidence on this issue (Dr. N.J.'s testimony) with respect to Resident 27. ALJ Decision at 25. We conclude that the ALJ reasonably relied on the surveyor's testimony in concluding that the medication error with respect to Resident 89 was significant.[24]

For the foregoing reasons, we uphold the ALJ's conclusion that Blossom South was not in substantial compliance with section 483.25(m)(2).

4. The ALJ's conclusion that Blossom South was not in substantial compliance with 42 C.F.R. § 483.35(i) is supported by substantial evidence and free of legal error.

In FFCL D, the ALJ concluded that Blossom South was not in substantial compliance with the part of section 483.35(i) ("Sanitary conditions") providing that "[t]he facility must—...(2) Store, prepare, distribute, and serve food under sanitary conditions…." The SOD stated that "food requiring time and temperature controls for safety was not properly cooled to inhibit the growth of disease-causing microorganisms[.]"[25] CMS Ex. 1, at 35-36. The ALJ found that, although Blossom South had policies for cooling hot foods, Blossom South did not follow those policies for two roasts cooked on July 17 and its cook did not understand the policies. ALJ Decision at 26-27. The policies required that hot foods be cooled from 135˚ to 70˚ F within two hours or less and then cooled from 70˚ to 41˚ F in four hours or less, for a total cooling time not exceeding six hours. P. Ex. O at 4-5 (documents titled "Cooling Procedure" and "Proper Cooling Guidelines"). At approximately 8:30 a.m. on July 18, the surveyor found that the temperature of two roasts in a walk-in refrigerator registered between 55˚ F and 55.8˚ F, as measured on her own and the facility's thermometers. CMS Ex. 1, at 36; CMS Ex. 20, at 7-8. The roasts had been cooked and taken out of the oven at approximately 11:00 a.m. the previous day. *Id*.

[24] Blossom South asserts that the surveyor's testimony should not be credited because the ALJ permitted the surveyor to testify by telephone, undermining Blossom South's "ability to effectively cross-examine" her. RR at 18. Blossom South does not explain its contention that it was unable to effectively cross-examine the surveyor other than to refer to "various 'no audible responses' recorded by the stenographer" and a delay of over ten minutes for the witness to receive CMS's exhibits. Reply at 7, citing Tr. at 32, 33-40. The surveyor's initially inaudible responses were repeated and do appear in the transcript, however. In addition, the transcript shows that the surveyor had the relevant exhibits available to refer to when she testified. We find no error, much less prejudicial error, in the ALJ's taking the surveyor's testimony by phone. In view of this conclusion, we need not determine whether, as the ALJ found, Blossom South "agree[d] to the telephone proceeding in the first place," thus "waiv[ing] its right to object." ALJ Decision at 4 n.3.

[25] The surveyor testified that temperatures between 45˚ F and 140˚ F "are in the food danger zone." Tr. at 111. The State Operations Manual states "Potentially Hazardous Foods …held in the danger zone for more than . . . 6 hours (if cooked and cooled) may cause a foodborne illness outbreak if consumed." SOD, App. PP, Tag F371 (identifying temperatures between 41˚ F and 135˚ F as in the food danger zone).

The surveyor interviewed the cook, who said that when she removes a roast from the oven, she cuts it into quarters, places it in the walk-in refrigerator, and checks the temperature "the next morning, to be sure the temperature goes down to about 40˚F." CMS Ex. 1, at 37; *see also* CMS Ex. 20, at 8. The cook added that she checks the roast before the end of her shift to see if the temperature has gone down to 155˚ F or 170˚ F. *Id*. When the Director of Food Services, who was present at the interview, asked the cook if that was right, the cook said, "Wait, after two hours I want the temperature to be down to 70˚F." *Id*. When asked how she kept track of this, the cook said that she covers the meat with foil and writes the time and temperature on top of the foil.[26] *Id*. The ALJ stated that "the cook did not seem to understand that the cooling had to be completed within six hours" and concluded: "That a facility cook did not know how to cool food safely created the potential for more than minimal harm and, by itself, put the facility out of substantial compliance with 42 C.F.R. § 483.35(i)[.]" ALJ Decision at 27.

Blossom South does not dispute that "the roast was not properly cooled and that improper cooling endangers resident health and safety." ALJ Decision at 26. Blossom South nevertheless argues that the regulation "does not impose liability upon facilities for an employee's purported lack of knowledge in correct cooling procedures" and that it was not liable here since it did not serve the roasts to residents. RR at 31. Blossom South argues further that the ALJ's finding that its cook did not understand or follow the policies for cooling foods is not supported by substantial evidence. *Id*. at 32.

As the ALJ indicated, it is irrelevant that the roasts were not served or whether they would have been served absent the surveyor's intervention. *See* ALJ Decision at 26 (stating that it seems likely that the roasts would have been served absent the surveyor's intervention, but that she need not resolve this question). The surveyor identified the cook she interviewed as "Cook #2 (regular cook)." CMS Ex. 20, at 8. Since Blossom South's regular cook did not understand the procedures for cooling hot foods set out in Blossom South's policies, she would likely have prepared other hot food for residents of the facility without following these procedures, and that food might have been served without having been properly cooled. This posed a potential for more than minimal harm since it is undisputed that food that is not properly cooled can cause foodborne illnesses.

[26] Although the roasts in question were found wrapped in foil (CMS Ex. 1, at 36), Blossom South does not contend, and there is no evidence, that any times or temperatures were written on the foil. (The SOD states that the Director of Food Services told the cook at the interview that "she should not cover the meat with foil because it would not help the cooling process." CMS Ex. 1, at 37. However, Blossom South's cooling policies do not specifically address the use of foil.)

Furthermore, substantial evidence supports the ALJ's finding that the cook did not understand the procedures for cooling hot foods in Blossom South's policies. In arguing to the contrary, Blossom South asserts that the cook understood that food should be cooled to a temperature of 70˚ F within two hours, notwithstanding her initial statement to the surveyor that she checks the roast before the end of her shift to see if the temperature has decreased to 155˚ F or 170˚ F. RR at 33. Even if the cook understood the first step in the cooling procedure, however, the ALJ found that she did not understand the second step, i.e., that "cooling needs to be completed within six hours." ALJ Decision at 27. Blossom South does not point to anything that undercuts this finding. In her corrected statement, the cook stated only that she would check a roast within two hours to make sure it had cooled to 70˚ F and then the next morning to make sure the temperature was down to about 40˚ F. Blossom South states that "[t]his is in accordance with the Facility's cooling policies, which require the final cooled temperature to be 41˚F or lower." RR at 32, citing P. Ex. O at 4. Both the cook's and Blossom South's descriptions of the policies omit the critical fact that a temperature of 41˚ F must be reached within six hours. Checking the temperature of a roast the morning after the day it was cooked could not establish whether the roast had in fact cooled down to 41˚ F within six hours. Even if the temperature of the roasts in question here had been 41˚ F or less when checked at 8:30 a.m. on July 18, that would not establish that the roasts had cooled to that temperature within six hours of the time the roasts were taken out of the oven the previous day.[27]

For the foregoing reasons, we uphold the ALJ's conclusion that Blossom South was not in substantial compliance with section 483.35(i).

[27] We agree with the ALJ that the finding that the cook did not understand the cooling procedures intended to prevent foodborne illness is, by itself, sufficient to establish that Blossom South was not in substantial compliance with section 483.35(i). ALJ Decision at 27. Thus, we need not address Blossom South's exceptions to the ALJ's finding that the conveyor belt on the tray line and the box beneath the belt were not sanitary, which the ALJ also concluded is, by itself, sufficient to establish that noncompliance. RR at 33-38; ALJ Decision at 28-29.

Conclusion

For the reasons explained above, we affirm the ALJ's decision upholding CMS's termination of Blossom South's Medicare participation.

/s/
Judith A. Ballard

/s/
Leslie A. Sussan

/s/
Sheila Ann Hegy
Presiding Board Member