

**Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division**

Oak Ridge Center
Docket No. A-17-97
Decision No. 2913
December 6, 2018

**DECISION REMANDING CASE TO
ADMINISTRATIVE LAW JUDGE**

Oak Ridge Center (Petitioner), a West Virginia skilled nursing facility (SNF), has appealed the June 13, 2017 decision by the administrative law judge (ALJ), who sustained an enforcement remedy imposed on Petitioner by the Centers for Medicare & Medicaid Services (CMS). *Oak Ridge Ctr.*, DAB CR4865 (2017) (ALJ Decision). This case arose from a Medicare compliance survey that found deficiencies in the care provided by Petitioner to residents with diabetes. Based on the survey's findings, CMS determined that Petitioner was not in substantial compliance with 42 C.F.R. § 483.25, which establishes a basic quality-of-care standard that a SNF must meet for each resident. CMS also found that Petitioner's noncompliance with section 483.25 had placed residents in "immediate jeopardy" from September 15, 2015 through May 12, 2016. As a remedy for the cited noncompliance, CMS imposed on Petitioner a \$5,900 per day civil money penalty (CMP).

Petitioner requested a hearing before the ALJ to challenge CMS's enforcement action. The parties then submitted documentary evidence and written testimony, but no in-person evidentiary hearing was held. Finding the "undisputed facts . . . more than adequate to prove immediate jeopardy level noncompliance by Petitioner," the ALJ granted summary judgment to CMS and sustained the CMP.

Petitioner's appeal presents two overarching issues: (1) whether Petitioner was out of "substantial compliance" with 42 C.F.R. § 483.25 from September 15, 2015 through May 12, 2016, as CMS had determined; and (2) whether CMS's finding that the noncompliance had placed residents in immediate jeopardy was clearly erroneous. We conclude that summary judgment in favor of CMS was appropriate on the first issue but that genuine disputes of material fact preclude summary judgment on the second. We therefore remand the case to the ALJ for further proceedings on the immediate-jeopardy issue.

I. LEGAL BACKGROUND

To participate in the Medicare program, a SNF must be in “substantial compliance” with participation requirements in 42 C.F.R. Part 483, subpart B (sections 483.1-.75).¹ 42 C.F.R. §§ 488.400, 483.1. A SNF is not in substantial compliance when it has a “deficiency” – that is, a failure to meet a participation requirement – that creates the potential for more than minimal harm to one or more residents. *Id.* § 488.301 (defining “substantial compliance”). The term “noncompliance,” as used in the applicable regulations (and in this decision), is synonymous with lack of substantial compliance. *Id.* (defining the term “noncompliance”). The participation requirement relevant to this case, found in 42 C.F.R. § 483.25, directs a SNF to provide each resident with “necessary care and services” to enable the resident to “attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.”

Compliance with Medicare participation requirements is verified through onsite surveys performed by state health agencies. *Id.* §§ 488.10(a), 488.11. A state survey agency reports any deficiency it finds in a Statement of Deficiencies (SOD). *Id.* §§ 488.325(f)(1), 488.331(a).

CMS may impose enforcement “remedies,” including CMPs (civil money penalties), on a SNF found to be not in substantial compliance. *Id.* §§ 488.400, 488.402(b), (c), 488.406. When CMS elects to impose a CMP, it sets the CMP amount based on, among other factors, the “seriousness” of the SNF’s noncompliance. *Id.* §§ 488.404(a), (b), 488.438(f). Seriousness is a function of the noncompliance’s scope (whether it is “isolated,” constitutes a “pattern,” or is “widespread”) and severity (whether it has created a “potential for” harm, resulted in “[a]ctual harm,” or placed residents in “immediate jeopardy”). *Id.* § 488.404(b). The most serious noncompliance is that which puts one or more residents in “immediate jeopardy.” *Id.* § 488.438(a) (authorizing the highest CMPs for immediate-jeopardy-level noncompliance); *Woodland Oaks Healthcare Facility*, DAB No. 2355, at 2 (2010).

A SNF may challenge a determination of noncompliance that has resulted in the imposition of a CMP (or other enforcement remedy) by requesting an ALJ hearing and appealing any unfavorable decision by the ALJ to the Board. 42 C.F.R. §§ 488.408(g)(1), 498.3(b)(13), 498.5(a)-(c). When CMS imposes a per-day CMP, a

¹ On October 4, 2016, CMS issued a final rule that amended the Medicare participation requirements for long-term care facilities published in 42 C.F.R. Part 483. Final Rule, *Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities*, 81 Fed. Reg. 68,688 (Oct. 4, 2016). Our analysis and decision are based on the version of the participation requirements that were in effect during May 2016, when the compliance survey supporting CMS’s enforcement action was performed. *Carmel Convalescent Hosp.*, DAB No. 1584, at 2 n.2 (1996) (applying the regulations in effect on the date of the survey and resurvey).

SNF may also challenge CMS’s determination that the noncompliance has placed residents in immediate jeopardy, but an ALJ and the Board must review that determination under a “clearly erroneous” standard. *Id.* § 498.60(c)(2). In addition, a SNF may challenge the reasonableness of the amount of any CMP imposed. *Lutheran Home at Trinity Oaks*, DAB No. 2111, at 21 (2007).

II. CASE BACKGROUND

From May 10 to May 18, 2016, the West Virginia Department Health and Human Resources (the state survey agency) performed a Medicare compliance survey of Petitioner. CMS Ex. 1A at 1. Among other things, the survey assessed how Petitioner’s staff had cared for five residents with diabetes. Those residents are identified here as Residents 75, 71, 55, 37, and 10.

Before outlining the survey’s findings, we provide some basic information (drawn from the record) about diabetes and its treatment. None of our factual statements concerning that topic are in dispute. Diabetes occurs when the body cannot adequately produce or use insulin, a pancreatic hormone that promotes cell absorption of blood glucose.² CMS Ex. 29, ¶¶ 17-19. Diabetes is characterized by hyperglycemia (abnormally high blood glucose). P. Ex. 2, at 11. For older adults, potential complications of diabetes include vascular damage, cognitive impairment, depression, dehydration, vision problems, and delayed wound healing and other skin problems. *Id.* at 11-12, 16. Diabetes treatment may include medication and insulin therapy, which lower the level of blood glucose.³ CMS Ex. 29, ¶¶ 23-28; CMS Ex. 26, at 16-17; P. Ex. 2, at 22, 25, 33. Elderly persons who receive treatment to lower blood glucose are prone to hypoglycemia, or abnormally low blood glucose – generally defined as a blood glucose level less than 70. P. Ex. 2, at 12, 39. For vulnerable elderly persons, untreated hypoglycemia has potentially serious

² There are two types of diabetes: type 1 (caused by the pancreas’s inability to make insulin); and type 2 (caused by the body’s resistance to, or inability to produce enough, insulin), the latter of which is prevalent among residents in long-term care facilities. CMS Ex. 29, ¶ 18; P. Ex. 2, at 11.

³ There are different types of manufactured insulin, characterized by how quickly they start to work, how long they work, and when they have “peak” effect. CMS Ex. 29, ¶¶ 24-26; CMS Ex. 26, at 7, 9; P. Ex. 2, at 33-35. Long-acting insulin is generally used “prophylactically” or prospectively to help keep a patient’s blood glucose levels within a normal range over a 24-hour period. CMS Ex. 29, ¶¶ 24-25. Short or rapid-acting insulin is “generally used to assist with blood glucose regulation after meals or to retrospectively correct hyperglycemia.” *Id.*, ¶¶ 24, 26. A “sliding-scale” regimen is a “short-term reactive method of treating hyperglycemia,” with the size of the dose corresponding to pre-defined blood glucose ranges. *Id.*, ¶ 27. “Because this type of treatment operates only retrospectively to correct hyperglycemia after it has already occurred, it does not reduce fluctuations in glucose levels.” *Id.* “Regularly-scheduled insulin is preferred over the use of [sliding-scale insulin] to try to maintain constant insulin levels in the body.” *Id.*

consequences. *Id.* at 39; CMS Ex. 29, ¶¶ 22, 32-34; Pet.'s Request for Review (RR) at 10 (acknowledging that hypoglycemia can be dangerous and "must be avoided"). For example, the condition may lead to confusion or other "altered mental status," which in turn may increase the risk of falls. CMS Ex. 29, ¶ 33; P. Ex. 2, at 12.

The goal of diabetes treatment generally is to keep a patient's blood glucose within a clinically appropriate range. CMS Ex. 29, ¶¶ 20, 23, 25, 28. "The normal blood glucose level of a healthy adult is generally accepted to be in the range of 80-110" mg/dl.⁴ *Id.*, ¶ 20. According to a clinical practice guideline issued by the professional association of medical practitioners who work in the long-term care setting, a blood glucose range of 100-200 "may be appropriate" for "older adults who have functional and cognitive impairments and limited life expectancy." P. Ex. 2, at 12 (further stating that it "may be appropriate to liberalize goals for glycemic control" for some patients in long-term or post-acute care settings); CMS Response Br. at 11-12 n.6 (acknowledging that there is no conflict between a statement by CMS's expert witness that the normal blood glucose range for a healthy adult is 80-100 and Petitioner's position that the normal range for an elderly long-term care resident is higher).

Based on its review of clinical records for Residents 75, 71, 55, 37, and 10 (dating back to September 2015) and interviews of Petitioner's nursing staff, the state survey agency found the following:

- On multiple occasions, nurses independently decided to "hold" (not administer) insulin that had been prescribed for a resident by a physician or nurse practitioner.
- Nurses did not consistently carry out a physician's order to notify the physician if the resident's blood glucose exceeded 300.
- On five occasions (involving two different residents), the nursing staff did not implement Petitioner's Hypoglycemia Protocol after discovering that the resident's blood glucose was less than 70.
- Due to an incorrectly transcribed physician order, the nursing staff failed to administer a resident's evening dose of long-acting insulin for eight consecutive days.

⁴ The units of measurement for blood glucose level are milligrams of glucose per deciliter (mg/dl) of blood. CMS Ex. 29, ¶ 17.

- In one instance, the nursing staff failed to obtain a hemoglobin A1c test result which had been ordered by the resident’s physician or nurse practitioner. (The hemoglobin A1c test measures a person’s average blood glucose level for the past two to three months.)

CMS Ex. 28, ¶¶ 15-36; CMS Ex. 27, at 4 (¶ 12), 5 (¶ 14), 6 (¶ 18); CMS Ex. 1A at 49-61; CMS Ex. 1B at 1-30; CMS Ex. 29, ¶ 35. Based on these findings, the state survey agency cited Petitioner for a “pattern” of noncompliance with 42 C.F.R. § 483.25.⁵ CMS Ex. 27, at 15 (¶ 13); CMS Ex. 28, at 11; CMS Motion for Summary Judgment (MSJ) at 2. The state survey agency also found that Petitioner’s pattern of noncompliance with section 483.25 had placed residents in immediate jeopardy; that the period of immediate jeopardy had begun in September 2015 and was not abated until the evening of May 12, 2016; and that Petitioner remained out of substantial compliance with section 483.25 and other requirements at a lower level of severity after May 12, 2016.⁶ CMS Ex. 27, at 8-9 (¶¶ 25-28), 10 (¶ 31), 15-16 (¶¶ 13-15); CMS Ex. 1A at 50-51; CMS Ex. 1B at 10-12. The state survey agency’s citation of immediate-jeopardy-level noncompliance, and the factual findings supporting it, are detailed in a SOD under survey tag F309. CMS Exs. 1A and 1B.

Adopting the state survey agency’s findings and conclusions, CMS imposed a \$5,900 per day CMP for the period September 15, 2015 through May 12, 2016 (the period of immediate jeopardy) and reduced the CMP to \$250 per day for noncompliance that continued after May 12, 2016. CMS Ex. 16, at 1, 6. The \$250 per day CMP accrued until August 29, 2016, the date on which Petitioner was found by the state survey agency to be back in substantial compliance with all participation requirements. *Id.* at 1.

⁵ When the survey in this case occurred, CMS’s guidance to state survey agencies stated that a SNF’s deficiencies constituted a “pattern” –

when more than a very limited number of residents are affected, and/or more than a very limited number of staff are involved, and/or the situation has occurred in several locations, and/or the same resident(s) have been affected by repeated occurrences of the same deficient practice. The effect of the deficient practice is not found to be pervasive throughout the facility.

State Operations Manual (CMS Pub. 100-07), Appendix P – Survey Protocol for Long term Care (prior to Rev. 106; effective April 4, 2014), sec. IV.C (attached to this decision as Appendix A).

⁶ The May 2016 survey found Petitioner noncompliant, at a level below the immediate-jeopardy level, with several participation requirements in addition to section 483.25. CMS Exs. 1A-1F. CMS concurred with the additional noncompliance citations, CMS Ex. 16, at 5-6, but none is at issue in this appeal.

Petitioner requested a hearing to challenge the determination that it was noncompliant with section 483.25. CMS responded with a summary judgment motion. In support of its motion, CMS submitted the SOD; a copy of the nursing and other medical records reviewed by the state survey agency; copies of relevant resident care policies (including Petitioner's Hypoglycemia Protocol); and evidence of published standards of nursing practice relating to medication administration and diabetes care. CMS also submitted declarations containing proposed testimony by: (1) the state agency surveyors who performed the May 2016 survey (CMS Ex. 27); (2) Lisa Pollard-Ray, a CMS surveyor who participated in the May 2016 survey in order to assess its quality (CMS Ex. 28); and (3) A. Jefferson Lesesne, M.D., a board-certified internist and geriatrician who offered opinions about the adequacy of the nursing care rendered to Residents 75, 71, 55, 37, and 10 and the potential for harm to those residents (and others) as a result of the cited noncompliance (CMS Ex. 29).

Petitioner countered the motion with (among other material): a 2010 clinical practice guideline, titled "Diabetes Management in the Long-Term Care Setting," issued by the AMDA – The Society for Post-Acute and Long-Term Care Medicine (AMDA)⁷; a similarly titled 2015 version of the AMDA clinical practice guideline⁸; and a 2016 "position statement" of the American Diabetes Association (ADA) titled "Management of Diabetes in Long-term Care and Skilled Nursing Facilities." P. Exs. 1-3. Petitioner also submitted declarations by Steven A. Levenson, M.D., Multifacility Medical Director at Genesis ElderCare (Petitioner's corporate owner) and a member of the committee that drafted the relevant AMDA clinical practice guideline (P. Ex. 30); Holly Estel, R.N., a vice-president of clinical operations at Genesis ElderCare (P. Ex. 31); and Naushira Pandya, M.D., Chair of the Department of Geriatrics at Nova Southeast University College of Osteopathic Medicine (Nova Southeast), Project Director of the Geriatric Education Center at Nova Southeast, and chair of the committee that drafted the AMDA clinical practice guideline (P. Ex. 32).

In briefing before the ALJ, Petitioner generally contended that CMS's noncompliance determination and immediate-jeopardy finding do not reflect "modern standards" of diabetes care, which, Petitioner said, emphasize "looser blood glucose control to minimize the risk" of hypoglycemia in the long-term care population. *See* Pet.'s Pre-Hearing Br. at 11; Pet.'s Reply to CMS's Motion for Summary Judgment (MSJ Response) at 4-6, 13. Petitioner further contended that the proposed testimony of Drs. Levenson and Pandya concerning those standards, and about the clinical significance of

⁷ Prior to 2014, this organization was known simply as the American Medical Directors Association (AMDA).

⁸ The 2015 version of the AMDA clinical practice guideline is titled "Diabetes Management in the Post-Acute and Long-Term Care Setting." P. Ex. 2.

blood glucose fluctuations and hyperglycemia in elderly nursing home residents, calls into question whether the cited deficiencies caused, or were likely to cause, harm to residents. MSJ Response at 3-5, 7-9, 14-15. In addition, Petitioner asserted that evidence of “ongoing interaction and communication” between its nursing staff and residents’ physicians or nurse practitioners negated the possibility that any nursing care “errors” could have harmed residents. *Id.* at 7. For these reasons, Petitioner urged the ALJ to deny the summary judgment motion and set the case for a hearing.

The ALJ found that Petitioner had “concede[d]” that it was in a state of noncompliance with section 483.25 between September 2015 and May 2016 but that CMS had in any event proffered evidence of “undisputed facts” demonstrating that Petitioner had violated the regulation by failing to provide diabetes care in accordance with physician orders and resident care policies. ALJ Decision at 2-3. The ALJ also found no basis for the claim that the cited deficiencies did not create a risk of harm to residents. *Id.* at 5-6.

Regarding the immediate-jeopardy issue, the ALJ stated that Petitioner’s “deficient care implicated multiple staff members . . . , affected multiple residents, and in some instances . . . constituted failure to provide necessary care over sustained periods of time” – amounting to a “systemic failure by Petitioner’s staff to understand the dangers and risks that diabetes posed to residents.” *Id.* at 3. The ALJ further stated that Petitioner’s “systemic failure to provide prescribed care to diabetic residents,” in violation of section 483.25, made it “likely” that those, and other similarly situated, residents would suffer “serious” complications or consequences of hypoglycemia and hyperglycemia. *Id.* at 3-4, 7-8, 10 (concluding that CMS had “offered undisputed facts showing that the systemic failures by Petitioner’s staff to provide requisite care to its residents created a likelihood of harm”).

In sum, the ALJ granted summary judgment to CMS on its claim that Petitioner was not in substantial compliance with 42 C.F.R. § 483.25 at the immediate-jeopardy level from September 15, 2015 through May 12, 2016. *Id.* at 3, 5. The ALJ also sustained the \$5,900 per day CMP imposed by CMS for that period. *Id.* at 10.

Petitioner then filed its request for review, objecting to the ALJ’s grant of summary judgment on the noncompliance and immediate jeopardy issues. (Petitioner’s appeal raises no issue concerning the reasonableness of the CMP.)

III. STANDARD OF REVIEW

We review the ALJ’s grant of summary judgment de novo. *Southpark Meadows Nursing & Rehab. Ctr.*, DAB No. 2703, at 5 (2016). “Summary judgment is appropriate when the record shows there is no genuine issue as to any material fact, and the moving party is entitled to judgment as a matter of law.” *Id.* The party moving for summary judgment

(here, CMS) has the initial burden of demonstrating the absence of a genuine dispute of material fact and that it is entitled to judgment as a matter of law. *NMS Healthcare of Hagerstown, LLC*, DAB No. 2803, at 6 (2017); *Bivins Memorial Nursing Home*, DAB No. 2771, at 4 (2017). A properly supported summary judgment motion obligates the non-moving party to proffer evidence of a genuine dispute of fact material to the outcome. *Southpark Meadows* at 5. In determining whether summary judgment is appropriate, we “view the evidence in the light most favorable to the non-moving party, drawing all reasonable inferences in that party’s favor.” *Avalon Place Kirbyville*, DAB No. 2569, at 7 (2014) (internal quotation marks omitted).

IV. ANALYSIS

Before addressing the compliance issues, we dispose of two points made by Petitioner concerning summary judgment practice. First, Petitioner notes that CMS did not include in its motion for summary judgment a statement of undisputed material facts “as is customary under Rule 56 [of the Federal Rules of Civil Procedure] when a party seeks summary disposition.” RR at 15. Instead, says Petitioner, “CMS basically argued that all of the allegations in the Statement of Deficiencies were true” *Id.* However, the Federal Rules of Civil Procedure do not govern this administrative proceeding, and the regulations which do govern (42 C.F.R. Part 498) contain no format or content requirements for summary judgment motions. *Cedar Lake Nursing Home*, DAB No. 2344, at 2 (2010). Furthermore, Petitioner does not argue that the summary judgment motion and SOD provided inadequate notice of CMS’s grounds for summary judgment.

Petitioner also contends that summary judgment may not be based on “unsworn” factual “allegations” in a SOD, which Petitioner calls a “charging document.” RR at 15. According to Petitioner, statements or findings in a SOD are not “evidence,” and CMS “must offer undisputed evidence” substantiating those statements or findings in order to support a summary judgment motion. *Id.* The Board has rejected that proposition, however, saying that a SOD “may constitute prima facie *evidence* of the undisputed facts asserted in it.” *Southpark Meadows* at 6 (italics in original, internal quotation marks omitted); *see also The Laurels at Forest Glenn*, DAB No. 2182, at 7 (2008) (noting that the SOD may function as both a “notice document” and as “evidence of the facts asserted therein” (internal quotation marks omitted)). In any event, CMS proffered nursing records and other evidence substantiating the relevant survey findings.

A. *The ALJ did not err in granting summary judgment on the finding that, from September 15, 2015 through May 12, 2016, Petitioner was not in substantial compliance with 42 C.F.R. § 483.25 in its care of five residents with diabetes.*

As it did before the ALJ, CMS contends in this appeal that Petitioner failed to provide Residents 75, 71, 55, 37, and 10 with “necessary care and services” in violation of section 483.25. The record reveals the following undisputed facts about the nursing care rendered to those residents.

Resident 75: Resident 75 was 76 years old at the time of the survey. P. Ex. 24. Apart from her diabetes, her chief medical problem was chronic obstructive respiratory disease, complications of which necessitated hospitalization and emergency room visits during 2015 and 2016. *See* P. Exs. 24-25; P. Ex. 27, at 1, 36. Her plan of care included the goal of avoiding “signs and symptoms” of both hypoglycemia and hyperglycemia. CMS Ex. 15C at 46.

Beginning in September 2015, Resident 75 had a physician’s order for a 15-unit dose of Humulin N (intermediate-acting insulin) each morning and a 10-unit dose at bedtime. CMS Ex. 1A at 54; CMS Ex. 15I at 49; P. Ex. 26, at 1; P. Ex. 28, at 9, 32-33. She also had an order for sliding-scale insulin and to notify the physician if her blood glucose level was less than 70 or greater than 400. CMS Ex. 15A at 53-54; P. Ex. 28, at 9, 32; P. Ex. 26, at 2. Reviewing Resident 75’s medication administration record (MAR), surveyors found that the nursing staff independently decided to “hold” (not administer) Resident 75’s morning (6:00 a.m.) dose of long-acting insulin on February 13, February 15, and February 17, 2016. CMS Ex. 1A at 54; CMS Ex. 28, ¶ 24; RR at 34-35. On those three dates, Resident 75’s 6:00 a.m. blood glucose levels were 89 (February 13), 91 (February 15), and 106 (February 17). CMS Ex. 1A at 55; P. Ex. 26, at 13. Surveyors found no contemporaneous documentation of the nursing staff’s reason(s) for withholding the prescribed insulin doses, no record that the nursing staff sought the approval of the resident’s physician to withhold them, and no record that the physician was notified about the withholding after the fact. CMS Ex. 1A at 54-55. In addition, surveyors identified three dates during February 2016 on which the nursing staff administered the 6:00 a.m. dose when the resident’s blood glucose level was between 92 and 98. *Id.* at 55.

Resident 71: An 86 year-old male with moderate to advanced dementia, Resident 71 was admitted to Petitioner’s facility in February 2016. CMS Ex. 14B at 1. Progress notes from mid-March 2016 reflect concern about his high, “uncontrolled” blood glucose levels, which prompted a nurse practitioner to prescribe insulin and order periodic blood glucose testing. CMS Ex. 14A at 41; P. Ex. 22, at 3; P. Ex. 21, at 4. On April 26, 2016, the nurse practitioner saw Resident 71 to assess what she called the resident’s

“suboptimal[ly] control[led]” diabetes and hyperglycemia. CMS Ex. 1B at 10; CMS Ex. 14A at 20-21. As a result of that visit, the nurse practitioner ordered the administration of 18 units of Lantus (long-acting insulin) every 12 hours – that is, 18 units in the morning, and 18 in the evening. CMS Ex. 1B at 10; CMS Ex. 14A at 9, 20; CMS Ex. 18, at 100. The nurse practitioner also instituted a temporary sliding-scale insulin regimen and directed staff to notify her if the resident’s blood glucose was less than 60 or greater than 400. CMS Ex. 14A at 20; P. Ex. 21, at 20, 27, 29. On May 3, the nurse practitioner observed that Resident 71’s blood glucose levels were still “suboptimally controlled” but showing “signs of improvement.” CMS Ex. 1B at 10; CMS Ex. 14A at 18. She continued the sliding-scale insulin regimen and issued the following order: “increase his morning (10am) Lantus dose to 20 units. Continue evening dose (10pm) of Lantus 18 units.” CMS Ex. 14A at 18; *see also* CMS Ex. 1B at 10; P. Ex. 22, at 7. However, the order to continue the evening 18-unit dose was erroneously transcribed on Resident 71’s medication administration record as an order to *stop* that dose; as a result, Resident 71 did not receive the evening dose of Lantus from May 3 until May 11, when the transcription error was caught. CMS Ex. 1B at 10; CMS Ex. 14A at 15, 17; RR at 32-33. After seeing Resident 71 on May 11, the nurse practitioner wrote that his “blood sugars have not improved, and have actually worsened with more episodes of hyperglycemia.”⁹ CMS Ex. 14A at 17. She issued new orders to mitigate that problem. *Id.*

Resident 55: Resident 55, who was 59 years old at the time of the survey and had type 1 diabetes, was admitted to Petitioner’s facility on March 30, 2016 for rehabilitation following a stroke. P. Ex. 14. Upon admission, she had physician orders for 62 units of Lantus (long-acting insulin) at bedtime, for sliding scale insulin (based on four daily blood glucose measurements), and to notify the physician if her blood glucose level was higher than 400. P. Ex. 16, at 2, 6; CMS Ex. 1B at 9. In reviewing a medication

⁹ Medication administration records (P. Ex. 22, at 7-9, 10, 12-14) show that between May 3 and the discovery of the transcription error on May 11, 2016 there were eight instances in which Resident 71’s blood glucose levels exceeded 300:

May 4, 2016	357 (11 a.m.)
May 5, 2016:	379 (4:00 p.m.)
May 9, 2016:	352 (11:00 a.m.) and 377 (4:00 p.m.)
May 10, 2016:	323 (11:00 a.m.) and 336 (4:00 p.m.)
May 11, 2016:	320 (11:00 a.m.) and 302 (4:00 p.m.)

administration record (MAR), surveyors found no indication on that record that Resident 55 had received her bedtime Lantus dose on April 10, 2016. CMS Ex. 1B at 9. The resident's MAR for that date confirms the survey agency's finding.¹⁰ P. Ex. 18, at 3; RR at 32.

Resident 37: Resident 37's diabetes diagnosis and residence at Petitioner's facility dated back to at least 2012. P. Ex. 6; CMS Ex. 1A at 57. In addition to diabetes, Resident 37, who was 81 years old when the survey occurred, had multiple medical problems, including effects of a stroke, essential hypertension, and chronic obstructive pulmonary disease. P. Ex. 6.

Resident 37 was hospitalized on August 7, 2015, complaining of weakness. CMS Ex. 1A at 55, 57. Just prior to the hospitalization, she was not taking diabetic medication, and her blood glucose was highly elevated (above 500). *Id.* at 56-57. She returned to Petitioner's facility on August 10, 2015. *Id.* at 55, 57. At that point, she had a physician order for five units of Humulin R (short-acting insulin) three times per day before meals (at 6:00 a.m., 11:00 a.m., and 4:00 p.m.) and 20 units of Lantus (long-acting insulin) at bedtime.¹¹ CMS Ex. 1A at 58; CMS Ex. 12C at 38; P. Ex. 9, at 2; P. Ex. 10, at 1, 3, 4. In late September 2015, a physician reevaluated Resident 37's diabetes, noting that her recent blood glucose levels had been between 78 and 165. P. Ex. 13, at 24. The physician continued the order for five units of Humulin R three times per day before meals (at 6:00 a.m., 11:00 a.m., and 4:00 p.m.) and for 20 units of Lantus at bedtime. *Id.*; P. Ex. 9, at 2; P. Ex. 10, at 6, 7. The physician also instructed staff to measure the resident's blood glucose twice a day and to notify her if the result was greater than 300 or less than 70. CMS Ex. 12C at 41; P. Ex. 8; P. Ex. 9, at 1; P. Ex. 10, at 5, 7; P. Ex. 13, at 24.

¹⁰ Surveyors made two additional findings regarding Resident 55, but neither of them is a basis for our decision. First, surveyors found that Resident 55 had not received her prescribed bedtime Lantus dose on May 4, 2016. CMS Ex. 1B at 9. In a brief submitted to the ALJ, CMS conceded the inaccuracy of that finding but asserted that Petitioner's staff had failed to administer the bedtime Lantus dose on *May 3* – pointing to page 24 of CMS Exhibit 13. *See* MSJ at 16 n.8; CMS Ex. 28, ¶ 9. But that page contains the MAR for the *sliding-scale* insulin order. The portion of the MAR for the bedtime Lantus dose is found on page 21 of CMS Exhibit 13, and that page shows that Lantus was administered at bedtime, as ordered, on May 3 (and on each day during the first nine days on May 2016). Second, surveyors found that, although Resident 55's blood glucose was 135 at 6:00 a.m. on April 11, 2016, the nursing staff did not administer the one unit of insulin called for by the sliding scale order. CMS Ex. 1B at 9. However, there is evidence – a handwritten note on, or appended to, the MAR – that the resident refused that dose. P. Ex. 18, at 4. The handwritten note does not appear on CMS's copy of the MAR, *see* CMS Ex. 13, at 23, but close inspection of CMS's copy indicates that the notation of medication refusal was partially masked or cut off in the copying process. CMS's motion for summary judgment and appeal brief fail to acknowledge the documentary evidence of medication refusal or discuss its potential implications. We therefore decline to rely on these findings in evaluating summary judgment.

¹¹ Resident 37 also had an order for sliding-scale insulin, but that order was discontinued in late September 2015. CMS Ex. 1A at 58; CMS Ex. 12C at 38, 40.

Surveyors found that, on 31 occasions between September 15, 2015 and April 19, 2016 (listed below), a nurse withheld Resident 37's prescribed 6:00 a.m. dose of short-acting insulin after checking the resident's blood glucose level:

<u>Date</u>	<u>Nurse</u>	<u>Resident's 6:00 a.m. Blood Glucose Level</u>
September 15, 2015	LPN5	78
September 16, 2015	LPN5	78
September 17, 2015	LPN5	109
October 9, 2015	LPN5	95
October 10, 2015	LPN5	78
October 15, 2015	LPN5	87
October 27, 2015	LPN5	86
November 1, 2015	LPN5	84
November 2, 2015	LPN5	90
November 11, 2015	LPN5	91
November 12, 2015	LPN5	92
November 13, 2015	LPN5	106
November 24, 2015	LPN5	94
December 8, 2015	LPN5	93
January 23, 2016	LPN5	86
January 24, 2016	LPN5	74
February 8, 2016	LPN5	84
February 11, 2016	LPN5	72
February 12, 2016	LPN5	82
February 16, 2016	LPN5	78
February 18, 2016	LPN5	87
February 21, 2016	LPN5	74
February 22, 2016	LPN5	94
February 25, 2016	LPN5	98
March 19, 2016	LPN5	97
March 20, 2016	LPN5	100
April 11, 2016	LPN21	86
April 13, 2016	LPN21	92
April 16, 2016	LPN21	89
April 17, 2016	LPN5	99
April 19, 2016	RN53	102

See CMS Ex. 1A at 58-61; CMS Ex. 1B at 1-2; CMS Ex. 27, at 5 (¶ 14). In each instance, surveyors found no record that the nurse consulted with the resident's medical practitioner in advance about withholding insulin, or any record that the practitioner was informed about the withholding after the fact. CMS Ex. 1A at 58-61; CMS Ex. 1B at 1-2. LPN5 was the nurse who withheld insulin on 27 of the 31 listed occasions. She told

surveyors that she withheld insulin when the resident's blood glucose level was low. CMS Ex. 1B at 2. However, surveyors found instances in which LPN5 administered the 6:00 a.m. dose when Resident 37's blood glucose was lower, equal to, or only slightly above the levels obtained on the dates she withheld that dose. *See, e.g.*, CMS Ex. 1A at 58, 60, 61 (indicating that LPN5 administered the 6:00 a.m. insulin dose on February 4, 2016 when Resident 37's blood glucose level was 92); CMS Ex. 1B at 1 (administration of 6:00 a.m. dose on March 16, 2016, after obtaining a blood glucose level of 91).

A medication administration record shows that, at 6:00 a.m. on October 20, 2015, Resident 37's 6:00 a.m. blood glucose was 66. CMS Ex. 1A at 50, 59-60; P. Ex. 10, at 7. Under Petitioner's then-existing Hypoglycemia Protocol, if a resident's blood glucose dropped below 70 (or some other physician-established threshold) and the resident was asymptomatic, the nursing staff was expected to take *all* of the following steps: (1) "[h]old all diabetic medications"; (2) "[a]dminister [a] rapidly absorbed simple carbohydrate"; (3) "[if] meal time, have patient eat meal"; (4) "[r]epeat blood glucose measurement in 10-15 minutes" and notify the physician "if no improvement"; (5) obtain "follow-up orders regarding diabetic medications and glucose monitoring"; and (6) "[f]ollow with meal or snack within one hour." CMS Ex. 1A at 59; CMS Ex. 9, at 2. Upon obtaining the sub-70 blood glucose reading on October 20, 2015, LPN5 withheld Resident 37's insulin. CMS Ex. 1A at 60. However, surveyors found "no evidence in the record [that] the hypoglycemia protocol was initiated for Resident #37" on that occasion. *Id.* at 50, 59-60. (Neither the SOD nor the medical records in evidence indicate whether the nursing staff complied with the standing order to notify the physician if Resident 37's blood glucose was less than 70. *Id.* at 39, 50, 59-60; *see also* CMS Ex. 28, ¶¶ 29-30.)

Resident 10: Resident 10, 84 years old at the time of the survey, had dementia, renal and vascular complications from her diabetes, congestive heart failure, and other medical problems. P. Ex. 4, at 2-3, 5, 54; CMS Ex. 1B at 2. Her blood glucose was at times not well-controlled. CMS Ex. 1B at 2, 7; CMS Ex. 11E at 21, 28, 31, 48, 57. A nurse practitioner informed surveyors that it was common for Resident 10's blood glucose level to fluctuate and that she was prone to hypoglycemia when her insulin was increased. CMS Ex. 1B at 7. Progress notes confirm that Resident 10's blood glucose "rang[ed] widely" and further indicate that a goal of her treatment was to "avoid any hypoglycemia[.]" CMS Ex. 11E at 21, 60.

Effective April 30, 2015 through at least April 28, 2016, Resident 10 had a physician's order to measure her blood glucose twice a day and to notify the physician if it was less than 70 or greater than 300.¹² CMS Ex. 1B at 3; CMS Ex. 1A at 9. In addition, Resident

¹² The upper threshold was increased to 400 on April 28, 2016, and to 450 on May 18, 2016. CMS Ex. 1A at 9; P. Ex. 4, at 104.

10 received daily insulin therapy and diabetes medication (Januvia). CMS Ex. 11E at 48, 57. Resident 10 also had a standing physician's (or nurse practitioner's) order to obtain a hemoglobin A1c test result every three months. CMS Ex. 1B at 4; P. Ex. 4, at 71; CMS Ex. 11E at 57.

Surveyors identified eleven instances between September 2015 and April 2016 in which they were unable to find a record of the nursing staff having notified Resident 10's medical practitioner when her blood glucose was higher than 300. CMS Ex. 1B at 4. Those instances were:

- September 4, 2015, at 4:00 p.m. when her blood glucose was 344
- September 25, 2015, at 4:00 p.m. when her blood glucose was 425
- October 26, 2015, at 4:00 p.m. when her blood glucose was 430
- November 2, 2015, at 4:00 p.m. when her blood glucose was 319
- December 27, 2015, at 4:00 p.m. when her blood glucose was 384
- February 21, 2016, at 6:00 a.m. when her blood glucose was 305
- February 26, 2016, at 6:00 a.m. when her blood glucose was 318
- March 3, 2016, at 4:00 p.m. when her blood glucose was 341
- March 10, 2016, at 4:00 p.m. when her blood glucose was 364
- March 31, 2016, at 6:00 a.m. when her blood glucose was 401
- April 19, 2016, at 6:00 a.m. when her blood glucose was 382

Id. at 4, 5-6. Surveyors also found that on 4:00 p.m. on February 26, 2016, Resident 10's blood glucose was 545, more than 200 units higher than the morning level of 318 that staff had failed to report to the physician. *Id.* at 5. The 4:00 p.m. result prompted staff to call the physician, who ordered a dose of Humalog (short-acting insulin). *Id.* at 5-6; CMS Ex. 11E at 31. Surveyors identified 12 other occasions on which the nursing staff notified Resident 10's medical practitioner of a blood glucose reading exceeding 300 and the practitioner responded by ordering short-acting insulin to treat the hyperglycemia. CMS Ex. 1B at 4-5.

In addition to the physician-notification lapses, surveyors identified four occasions – at 6:00 a.m. on January 10, January 16, February 29, and April 6, 2016 – in which there was no record of the nursing staff having followed its Hypoglycemia Protocol after discovering that Resident 10's blood glucose was less than 70. CMS Ex. 1B at 6; CMS Ex. 27, at 6 (¶ 18). On one of those occasions (April 6), Resident 10's blood glucose level was 48 (P. Ex. 4, at 94); on the other three occasions, her blood glucose was between 67 and 69 (*id.* at 84, 88). (Again, nothing in the SOD or record before us indicates whether the nursing staff carried out the standing order to notify the physician if Resident 10's blood glucose fell below 70. CMS Ex. 1B at 6; CMS Ex. 28, ¶¶ 27, 30.)

Finally, surveyors found that Petitioner did not comply with a physician's order to obtain a hemoglobin A1c test result every three months (July, October, January, and April) for Resident 10. CMS Ex. 1B at 4, 7. The resident had an A1c test on July 15, 2017; the result was "elevated" (9.9).¹³ *Id.* at 7. The test was repeated on August 3, 2017, yielding another elevated result (9.0). *Id.* The next test was scheduled for October 30, 2015. *Id.* Petitioner was unable to produce documentation of the A1c test having been performed on or around that date. *Id.* Petitioner did not obtain another A1c test result until January 6, 2016, and that result was 8.7. *Id.*

Surveyors interviewed members of Petitioner's nursing staff about diabetes care practices. *See* CMS Ex. 1B at 7-9; CMS Ex. 27, at 6-8. A nurse identified as RN51 discussed the withholding of insulin:

[W]hen asked how the nurses determined whether or not to hold a resident's scheduled insulin if there was not a physician established parameter for the order. She said it was a nursing judgment. She stated it was very discretionary depending on a lot of things like the resident's blood sugar, if the resident ate, and what the resident ate. She stated the nurses knew the residents, and how their blood sugars behaved, so it was at the nurse's discretion whether to hold the insulin. She indicated if a resident was not to have anything by mouth because of a scheduled procedure they would not give any of diabetic medications including insulin. She indicated that they learned about this in nursing school and it was really just up to the nurse. When asked if the nurse should contact the physician, she stated, "No it is a nursing judgement."

CMS Ex. 1B at 8. Another nurse, RN53, told surveyors that –

if she made the decision to hold the resident's insulin, she would call the doctor. She stated that it would depend on the resident's blood sugar and if the resident had eaten and what the resident had eaten, but if she did not feel comfortable administering the insulin she would call and notify the physician so the physician could make the final decision.

¹³ "Healthy people will have an A1c within a range of 4-5.7%." CMS Ex. 29, ¶ 36. "An A1c value of 5.7-6.4% reflects an increased risk for diabetes (prediabetic)." *Id.* "Persons with diabetes have an A1c of 6.5% or higher." *Id.* "An A1c value of 9% or above indicates the individual's diabetes is poorly controlled and marked by frequent incidents of high blood glucose levels." *Id.*

Id. Petitioner’s Director of Nursing also provided statements to the surveyors on the subject:

During [his] interview . . . , when asked about holding a resident’s scheduled insulin when there was no physician ordered low parameter, the Director of Nursing (DON) said that to hold or not to hold a resident’s insulin was a nursing judgement. He did state however, the expectation would be that the nurse would call the provider and notify them that they felt the insulin should be held and why and let the provider give the final answer on whether or not to hold the resident’s insulin. He stated the nurse should document the conversation with the provider in the medical record.

Id. at 8-9.

In her declaration, CMS surveyor Lisa Pollard-Ray stated that a nurse violates accepted standards of nursing practice by holding prescribed insulin without first conferring with the physician:

. . . [B]asic nursing standards of practice for medication administration require that the nurse adhere to the physician order. CMS Ex. 24 at 9. . . . Compliance with the physician order is necessary to ensure that patients receive medications as prescribed and within the time prescribed in the appropriate environment. (CMS Ex. 24 at 21).[¹⁴]

In particular, because insulin is a “time-critical medication,” the nurse must give priority to ensuring that it is administered to the patient in a timely manner. (CMS Ex. 24 at 23). Indeed, standards of care guidelines regarding caring for patients with Diabetes Mellitus require, among other things, that the nurse “[m]ake sure that appropriate insulin dosage is given at the right time and in relation to meals and exercise.” (CMS Ex. 26 at 24). . . .[¹⁵]

In my expert opinion, according to standard nursing practice, if the resident presented in such a manner that, in the nurse’s judgment, the medication should not be given, then “the nurse must clarify the medication order with the prescribing healthcare provider.” (CMS Ex. 24 at 41).

¹⁴ In making these statements, Nurse Pollard-Ray indicated that she was relying on a “standard nursing manual” titled *The Fundamentals of Nursing* (by Potter and Perry). CMS Ex. 28, ¶ 17.

¹⁵ Nurse Pollard-Ray indicated that her statements regarding nursing care for diabetes patients are based (in whole or part) on *The Lippincott Manual of Nursing Practice*, a “standard nursing manual.” P. Ex. 28, ¶ 18.

Therefore, by disregarding the physician orders for insulin, [LPN53] failed to follow standard nursing practice regarding medication administration and the standards of care guidelines regarding caring for patients with Diabetes Mellitus. . . .

[The surveyors'] interview with [RN51], as set forth in the [SOD], demonstrated that [RN51] erroneously believed that she was authorized to disregard the physician orders and to make her own "nursing judgment" to hold the insulin, without notifying the physician that she was holding the medication. CMS Ex. 1B at 8.

As with the case of LPN[5], [RN51]'s interview statements reflect an incorrect comprehension of the standard nursing practice concerning proper medication administration because it would violate the standard nursing practice concerning proper medication administration for an RN to hold insulin without notifying the physician.

[The surveyors'] interview with RN[53] and the Director of Nursing demonstrated that those two nursing professionals at Oak Ridge Center correctly understood their responsibility as a nurse to notify the physician in a situation where they believed it was appropriate to hold the insulin for a resident. CMS Ex. 1B at 8-9. However, it is problematic that two out of four nurses who were interviewed by the surveyors incorrectly understood their responsibilities regarding proper medication administration and physician notification.

CMS Ex. 28, at 6-7 (paragraph numbers omitted).

Petitioner's medical experts "agree[d] that nurses should follow all physician orders as written and, except in some emergencies, should consult with a medical practitioner before modifying an order or withholding a medication." P. Ex. 30 (Levenson Decl.) at 3; P. Ex. 32 (Pandya Decl.) at 3. Similarly, Petitioner's nursing expert testified in her declaration that "nurses should follow all physician orders as written and, except in emergencies, should consult with a physician before modifying an order or withholding a medication even if the nurse thinks she knows what the physician will order." P. Ex. 31 (Estel Decl.) at 4. She also noted that Petitioner's own policies instructed nurses to contact a resident's physician before implementing a change to any medication administration order. *Id.* at 3.

Dr. Lesesne, CMS's medical expert, testified that hyperglycemia "may produce both immediate and long term consequences." CMS Ex. 29, ¶ 29. He explained the short-term consequences as follows:

The immediate short term consequences of hyperglycemia include dehydration, low blood pressure, and altered mental status. The underlying medical condition is dehydration which often manifests itself with symptoms of low blood pressure or the symptom of confusion/altered mental status. This symptom of confusion/altered mental status can occur particularly rapidly in the geriatric population. In the context of the hyperglycemic episode, the high blood glucose causes diuresis (i.e., abnormal water wasting in the kidneys) resulting in frequent or excessive urination. The water imbalance thus causes dehydration because the individual is excreting more water than they are taking in. The homeostatic response of older adults declines as people age. Therefore, elderly adults lose their ability to autocorrect problems like dehydration and low blood pressure. Consequently, dehydration in a frail elderly diabetic individual carries serious consequences because those individuals have great difficulty returning to homeostatic balance of their hydration level. As such, dehydration in an elderly individual poses a significant risk of low blood pressure and altered mental status due to the individual's inability to return to homeostasis effectively. In particular, it bears mentioning that because the homeostatic response of individuals declines and slows down as people age, elderly individuals carry a higher risk of becoming rapidly dehydrated. Moreover, once sick elderly individuals become dehydrated they are at far greater risk than younger healthier individuals of the consequences of dehydration. The signs and symptoms of hyperglycemia are related to the absolute value of the blood sugar and the duration of the hyperglycemic episode. Therefore, extremely high blood sugar levels far above the normal range that are not timely addressed are more likely to result in serious immediate symptoms than blood sugar levels that are just slightly above the normal range.

Id., ¶ 30. According to Dr. Lesesne, the long-term consequences of hyperglycemia –

include long term damage, dysfunction, and ultimate failure of various bodily organs, especially the kidneys, heart, brain, skin, eyes, nerves, and blood vessels. The excess glucose in the blood stream causes vascular damage which, in turns, damages the body's organs. Additionally, the vascular damage that results from hyperglycemia has the potential to exacerbate and make worse any other underlying medical conditions from which the individual suffers.

Id., ¶ 31.

In addition, Dr. Lesesne stated that hypoglycemia (abnormally low blood glucose) is “a very serious condition” whose symptoms include confusion and weakness, and that hypoglycemia “can lead to coma and death” if not treated quickly. CMS Ex. 29, ¶ 22. Because the adverse consequences of hypoglycemia “can develop rapidly,” said Dr. Lesesne, the “standard of practice for addressing incidents of hypoglycemia requires that, above all else, health care providers . . . address/respond to hypoglycemic episodes immediately.” *Id.*, ¶ 33. Dr. Lesesne further stated that “most nursing homes develop and implement a Hypoglycemia protocol to ensure” that its staff responds “immediately and appropriately the emergent needs of an individual experiencing a hypoglycemic incident,” and that “[i]ndividuals who experience hypoglycemic incidents are particularly at risk for accidents and injury secondary to symptoms of confusion and altered mental status due to the low blood sugar.” *Id.*

Noting that he had reviewed the “clinical records” of the five residents whose care is at issue, Dr. Lesesne stated that Residents 75, 55, and 37 were “subject to all of the risks involved with hyperglycemic episodes” as a result of the nursing staff’s failure to administer insulin according to physician or nurse practitioner orders. CMS Ex. 29, ¶¶ 16, 45, 48, 50, 53. Dr. Lesesne further stated that the nursing staff’s failure to administer prescribed insulin to those residents made it “highly likely that uncontrolled blood sugars would contribute to and exacerbate” the residents’ other medical problems (cardiac and vascular disease in Resident 75; cerebral vascular disease in Resident 55; and cardiac disease in Resident 37). *Id.*, ¶¶ 48, 51, 54. He characterized the risk of harm to Resident 37 as “high” because of the “frequency and duration of the nursing staff[’s] failure to ensure that [the resident] received insulin as ordered.” *Id.*, ¶ 47.

Concerning the care provided to Resident 71, Dr. Lesesne stated that “failure on the part of the Oak Ridge nursing staff to provide the daily dose of long acting insulin to Resident 71 for eight consecutive days resulted in actual harm” – specifically, multiple episodes of hyperglycemia – to the resident. *Id.*, ¶ 62. “In addition to actual harm,” said Dr. Lesesne, “Resident 71 was subject to all of the risks involved with hyperglycemic episodes[.]” *Id.*, ¶ 63. Dr. Lesesne noted that Resident 71 had coronary artery disease, hypertension, high cholesterol, and vascular disease, and that “any failure to attempt to control the resident’s blood sugar would have worsened” those medical conditions. *Id.*, ¶ 64.

Regarding staff’s multiple failures to notify Resident 10’s medical practitioner of blood glucose levels exceeding 300, Dr. Lesesne testified that –

[i]t is extremely important for nursing staff to notify the physician of a blood glucose level that is so greatly outside of the normal range so that the physician can have the opportunity to develop the best response to this significant change in the resident’s physical condition. For example, the

physician may need to implement measures to manage the resident's diabetes and bring the resident's blood glucose level down to a more normal range. Additionally, the extremely elevated blood glucose level may be a symptom of a larger or different problem with the resident which the physician may need to investigate further. The failure on the part of Oak Ridge nursing staff to notify the physician of all of these instances of hyperglycemia constituted a failure to provide the necessary diabetes management care and services to the diabetic residents of Oak Ridge. . . . In my expert medical opinion, the failure to consistently notify physicians when blood glucose was above a certain ordered threshold . . . resulted in a risk of serious bodily harm or death to all diabetic residents. Because [Resident 10] was already hyperglycemic, the failure to notify the physician of the resident's existing hyperglycemia put the resident at risk that the blood sugar level would escalate further and subject the resident to more serious immediate and long term consequences. . . .

Id., ¶¶ 68-69.

Dr. Lesesne stated that Petitioner's failure to obtain a hemoglobin A1c test result for Resident 10 in October 2015 was a failure to provide necessary diabetic care because it "deprived Resident 10's care planning team of valuable data it needed to manage a complex diabetes case effectively[.]" *Id.*, ¶ 71. He further explained:

[T]he last two HGA1c tests prior to the test Oak Ridge Center failed to perform indicated outlier values of 9.9 on July 15, 2015 and 9.0 on August 3, 2015. Thus, the failure to follow up when the facility staff had specific knowledge that Resident 10's blood sugars were not being well controlled over time put the resident at risk that her blood sugars would remain out of control, given that the physician did not have the HGA1c data to try to control the blood sugar levels more effectively. The single act of failing to perform the HGA1c test [in October 2015] did not directly pose a risk of serious bodily harm or death to Resident 10. However, that deficient practice in combination with the other failures to manage Resident 10's diabetes posed a risk of serious bodily harm and/or death because the failures, in combination, put the resident at high risk of hyperglycemia and hypoglycemia both of which carry the risk of serious bodily harm or death.

Id., ¶ 72.

Finally, Dr. Lesesne testified that Petitioner’s failure to implement or fully implement its Hypoglycemic Protocol after obtaining blood glucose levels below 70 “posed a risk of serious bodily injury or death for Residents 10 and 37.” *Id.*, ¶ 60. In those instances, the staff “failed to address or treat the residents’ hypoglycemia,” which, said Dr. Lesesne, “is such a serious condition it can be life threatening and . . . can cause a variety of serious symptoms including confusion, weakness, flushing/sweating, coma, and death.” *Id.*

The undisputed facts and survey findings establish that, multiple times between September 2015 and May 2016, Petitioner’s nursing staff failed to carry out medical practitioners’ orders for treating or monitoring residents’ diabetes – in particular, by unilaterally deciding, contrary to accepted nursing practice standards, to withhold prescribed insulin to Residents 37 and 75; by failing to provide prescribed insulin to Residents 55 and 71; by failing to report episodes of abnormally high blood glucose levels experienced by Resident 10; and by failing to obtain a hemoglobin A1c test result for Resident 10.

It is also undisputed that the nursing staff failed to implement Petitioner’s Hypoglycemia Protocol when testing revealed blood glucose levels lower than 70 for Residents 37 and 10. Petitioner does not dispute that those test results obligated its staff to implement the protocol. *See* RR at 24-25 (discussing Resident 10) and 29-31 (discussing Resident 37). Petitioner asserts that Residents 10 and 37 never exhibited “signs or symptoms” of hypoglycemia and that the AMDA clinical practice guideline “provide[s] that nurses need not notify physicians of *asymptomatic* single instances of uncomplicated hypoglycemia.” RR at 24-25 (*italics added*). These assertions do not help Petitioner. The Hypoglycemia Protocol indicates that it must be initiated in response to *any* blood glucose reading lower than 70, regardless of whether the resident manifests symptoms, and requires actions (such as administration of a rapidly absorbed carbohydrate and prompt rechecking of the resident’s blood glucose) besides physician notification. Also, the protocol is not inconsistent with the AMDA guideline (as Petitioner describes it): the protocol requires physician notification of asymptomatic hypoglycemia *only if* the nursing staff’s efforts to boost the resident’s blood glucose level above 70 are unsuccessful. P. Ex. 9, at 1. That requirement is consistent with the AMDA guideline’s recommendation that a practitioner be called if the resident has “consecutive” blood glucose readings lower than 70. P. Ex. 2, at 41.

Petitioner does not deny that its failures to carry out treatment orders and follow a resident care policy violated section 483.25. *See* RR. Indeed, the Board has held that the “necessary care and services” required by that regulation “include services ordered by the physician.” *Life Care Ctr. of Tullahoma*, DAB No. 2304, at 34 (2010), *aff’d*, *Life Care Ctr. Tullahoma v. Sec’y of U.S. Dept. of Health & Human Servs.*, 453 F. App’x 610 (6th Cir. 2011). That holding logically encompasses services ordered by non-physician

medical practitioners (such as nurse practitioners) whose scope of practice permits them to prescribe medical or nursing care. The Board has also held that “necessary care and services” include the care called for by an established resident care policy, such as the Hypoglycemia Protocol. *Tullahoma*, DAB No. 2304, at 34; *Laurels at Forest Glenn* at 6 (finding a SNF’s failure to adequately monitor resident’s blood sugar levels and follow facility protocol for notification of low blood sugar levels was a failure to provide necessary care and services); *id.* at 18 (stating that CMS “may reasonably rely” on a SNF’s resident care policy “as evidencing [the SNF]’s understanding of what must be done to attain or maintain residents’ highest practicable” well-being).

Petitioner does say that we should infer, from the available clinical records, that its nursing staff *always* complied with Resident 10’s physician-notification order (when the resident’s blood glucose level rose above 300) and that its staff withheld insulin only after consulting with a resident’s medical practitioner, even though the staff’s records do not reflect such compliance or consultation. More specifically, Petitioner suggests that because those records show that physicians or nurse practitioners regularly visited the facility, saw residents, and communicated with the nursing staff about residents, a finder of fact could reasonably presume that staff members must have timely consulted with or notified the residents’ medical practitioners when necessary to comply with diabetes treatment or management orders. *See* RR at 2, 6-8, 12, 24 (stating that Petitioner’s “evidence should have created the inference that [its] nurses *were* communicating with residents’ physicians and nurse practitioners” about diabetes management “even if they did not document every such communication in a nursing note,” and that it is “very likely that nurses actually did notify nurse practitioners of most or all of the [] instances of high blood sugar” (italics in original)). However, the proposed inference is pure conjecture. Petitioner does not point to documentary evidence that its nursing staff were in contact (by phone, fax, or other method) with the residents’ physicians or nurse practitioners *about any subject*, much less the residents’ diabetes, on the days when the staff’s obligation to notify or consult with a medical practitioner arose. Moreover, Petitioner offers no testimony from nurses, physicians, or nurse practitioners asserting that they communicated about Resident 10’s high blood glucose levels or about withholding insulin from Residents 75 and 37. In fact, as noted above, it is uncontested that at least one of Petitioner’s nurses (RN53) informed surveyors that it was not her normal practice to notify the physician when she deviated from insulin orders. P. Ex. 1B at 8. Absent evidence that its nursing staff members were in contact with medical practitioners on the days in question about these residents’ conditions, Petitioner’s allegation that it timely complied with its consultation and notification obligations is at best speculative. In the summary judgment context, we are obligated to draw only “reasonable” inferences from the record, and inferences based on speculation are not reasonable. *Dumas Nursing and Rehab., L.P.*, DAB No. 2347, at 18 (2010).

Petitioner’s violation of section 483.25 – that is, its failure to carry out diabetes care orders and implement the Hypoglycemia Protocol – constituted lack of substantial compliance if it had the “potential” to cause more than minimal harm. On that subject, Dr. Lesesne testified in his declaration that Petitioner’s failure to administer prescribed insulin to Residents 75, 71, 55, and 37 placed those residents “at risk of developing hyperglycemia” and of experiencing harmful complications associated with that condition, including dehydration, low blood pressure, altered mental status, vascular damage (affecting organs), and worsening of coexisting medical problems. CMS Ex. 29, ¶¶ 45, 47-48, 50-51, 53-54, 63-64. Dr. Lesesne also testified that the nursing staff’s failure to comply with an order to notify a medical practitioner about Resident 10’s 300-and-above blood glucose levels likewise posed a risk of harm from hyperglycemia and made it possible that the resident’s blood glucose would “escalate further and subject the resident to more serious immediate and long term consequences.” *Id.*, ¶ 69. In addition, Dr. Lesesne testified that Residents 37 and 10 were subjected to a “risk of serious harm or death” when the nursing staff improperly failed to implement the Hypoglycemia Protocol. *Id.*, ¶ 60. These medical opinions, and the undisputed facts upon which the opinions are based, establish that Petitioner’s violation of section 483.25 had at least the potential for more than minimal harm.

Petitioner offered opinions from its medical experts about the likelihood, nature, and seriousness of harm arising from its regulatory violation. While those opinions bolster its claim that summary judgment was inappropriate on the immediate-jeopardy issue (which we discuss in the next section), they do not raise a genuine factual dispute material to our decision about whether Petitioner’s violation of section 483.25 created a potential for more than minimal harm (the severity level necessary to support a finding of lack of substantial compliance).

Petitioner’s core argument is that current standards of diabetes care for long-term care residents have changed significantly from prior practice and that those changes are material to any finding about whether the deficient nursing care cited by the surveyors had the potential to harm residents. RR at 10; *see also* P. Ex. 30 (Levenson Decl.) at 4 (asserting that the AMDA clinical practice guideline “should provide the framework for discussion and analysis of [the cited] nursing errors”). According to Petitioner, the AMDA clinical practice guideline and ADA position statement, together with the testimony of its medical experts (Drs. Levenson and Pandya), “illustrate that the current medical consensus is that there is minimal risk for a nursing facility resident to have relatively high sustained blood sugar levels (hyperglycemia)”; that “overly aggressive control of asymptomatic *high* blood sugar (hyperglycemia) is an important risk factor for *low* blood sugar (hypoglycemia), which can present atypically (and thus be hard to diagnose) in this population”; that “the focus of modern standards of care is on looser blood glucose control to minimize the risk of *low* blood sugar (*hypoglycemia*)”; and that

the AMDA and ADA “now recognize that the desirable target range in long term care residents is considered to be between 100 and 200, that is, a much higher level for nursing facility residents than in otherwise healthy adults.” RR at 20-21. Moreover, says Petitioner, the AMDA specifically recognizes that “isolated blood sugar test results” higher than the target ranges identified by CMS’s medical expert (80-110) and by the AMDA practice guideline and ADA position statement (100-200) “are not necessarily problematic.” RR at 21.

In a nutshell, Petitioner’s apparent position is that hyperglycemia poses no risk of harm, or at worst a risk of only “minimal” harm, to long-term care residents with diabetes (the avoidance of hypoglycemia being the primary treatment objective), and thus any nursing error or omission that could have caused such a resident to experience an episode of untreated hyperglycemia – such as failing to administer prescribed insulin – did not meet the severity threshold for a finding of noncompliance. RR at 12, 21 (stating that “many” of the nursing lapses “posed no risk of harm at all” and in some instances may have protected residents against harm); *id.* at 31 (asserting that there was no “plausible risk of harm” to R37 due to withholding of insulin because that action was taken only when resident’s blood glucose was “low normal” and with the intent to minimize the risk of hypoglycemia). Referring to the withholding of insulin, Petitioner asserted that “missing an occasional dose of insulin might cause blood sugar to rise temporarily . . . , but transient hyperglycemia in this [elderly nursing home] population is not harmful (and subsequent doses of insulin will be enough to address chronic hyperglycemia).” RR at 22.

The suggestion that hyperglycemia poses no risk of significant (more than minimal) harm to long-term care residents is not supported by the AMDA and ADA publications upon which Petitioner and its medical experts rely. Those publications do indicate that avoidance of hypoglycemia is an important (and perhaps the most important) factor in deciding how tightly to control a long-term care resident’s blood glucose level. *See* P. Ex. 2, at 12 (noting that hypoglycemia risk is a factor to be considered in setting goals for glycemic control); P. Ex. 3, at 3 (stating that “glycemic goals for patients in LTC are guided by preventing hypoglycemia while avoiding extreme hyperglycemia”). However, neither publication suggests that hyperglycemia, be it chronic or episodic, is a benign condition in long-term care residents, or that preventing or reducing the frequency of hyperglycemic events is clinically inappropriate or generally unnecessary to maintain a resident’s well-being. P. Ex. 2, at 41 (discussing a “systematic facility approach to diabetes management” that can reduce the frequency of episodes of both hypoglycemia and hyperglycemia). To the contrary, both publications plainly indicate that hyperglycemia can adversely affect a long-term resident’s cognitive and physical functioning. The ADA position statement states, for example, that “persistent hyperglycemia increases the risk of” various problems, including dehydration, electrolyte

abnormalities, urinary incontinence, and falls. P. Ex. 3, at 3. Similarly, the AMDA guideline states that hyperglycemia may “decrease pain thresholds, impair vision, impede wound healing, and increase risks for falls,” and that it may also “impair cognition” in patients with dementia. P. Ex. 2, at 12; *see also id.* at 23 (stating that “[c]hronic hyperglycemia greater than 200 mg/dL may be associated with osmotic diuresis, fluid and electrolyte disturbances, increased risk for infection, [and] impaired immune function”). In addition, the AMDA guideline indicates that its recommendations aim to reduce or minimize “hyperglycemic events,” implying that doing so will avoid potential harm to patients. *Id.* at 15 (“recommend[ing] processes” whose benefits include “[f]ewer . . . hyperglycemic events”) and 22-23 (indicating that an individualized care plan “may include,” if “clinically appropriate,” establishing “appropriate target ranges for blood glucose control”).

Petitioner’s statement that the AMDA and ADA recognize a “desirable” blood glucose range of 100 and 200 for elderly long-term care residents – a summary statement repeated by its medical experts¹⁶ – oversimplifies the actual text of those organizations’ recommendations. The AMDA and ADA publications set out a general “framework” for determining or “considering” an appropriate level of blood glucose control for an elderly long-term care resident. P. Ex. 3, at 3-4; P. Ex. 2, at 23-24. Although those publications indicate that more relaxed or “flexible” goals for controlling blood glucose (within a target range of 100 to 200) may be appropriate for such a resident, the recommended framework does not dictate what levels of blood glucose are necessarily “desirable” (or achievable) in all circumstances or for all residents. The AMDA practice guideline explains that, for any specific resident, an appropriate blood glucose target range may be lower than 100-200 depending on the resident’s “coexisting chronic illnesses” (which may affect the level of blood glucose), cognitive status, “hypoglycemia vulnerability,” fall risk, life expectancy, patient preferences, and other patient-specific factors. P. Ex. 2, at 24 (specifying fasting and bedtime blood glucose targets for three “health status” categories and noting that “not every patient will clearly fall into a particular category”). Furthermore, both publications emphasize the need to “individualize” treatment and goals to minimize potential complications of the disease. P. Ex. 3, at 3, 4 (stating that the “clinical complexity and psychosocial heterogeneity of the older population in [long-term care] facilities require innovative thinking and individualized strategies to care for them”); P. Ex. 2, at 12 (stating that “goals for glycemic control and risk-factor management should be based on the individual patient’s overall health” and other factors) and 22 (discussing the development of an individualized diabetes care plan).

¹⁶ *See* P. Ex. 30 (Levenson Decl.) at 5 and P. Ex. 32 (Pandya Decl.) at 6.

Even assuming that a target blood glucose range of 100-200 would have been appropriate for all of Petitioner's residents, accepting that assumption would not tend to discredit or refute CMS's testimonial evidence about the potential for harm created by certain nursing errors. That blood glucose levels up to 200 are not problematic for a long-term care resident does not undercut evidence that Petitioner's residents were at risk of harm from failures to follow the Hypoglycemia Protocol. Nor does that proposition address the potential consequences of nursing errors that involved, or resulted in, a failure to treat blood glucose levels above 300. Those errors included the week-long failure to administer long-acting insulin to Resident 71, who experienced three consecutive days of blood glucose levels higher than 300 (*see infra* footnote 8); and the nursing staff's multiple failures to notify a medical practitioner when Resident 10's blood glucose exceeded 300, omissions that deprived the practitioner of a timely opportunity to prescribe appropriate treatment (as happened in other instances). Petitioner's medical experts did not discuss the nursing error involving Resident 71, nor did they say that the physician-notification lapses involving Resident 10 created no potential for harm.¹⁷

Drs. Levenson and Pandya did say that, in evaluating whether the nursing staff's failure to report Resident 10's abnormally high blood glucose values posed a risk of harm, one must consider whether the notification order issued by the resident's physician conformed with the AMDA's recommendation that physicians be notified of blood glucose values above 300 only if that result is obtained on consecutive days or if the resident is symptomatic. P. Ex. 30, at 6 (stating that the "fact that some of the [physician-notification] orders at issue do not necessarily reflect [the] latest guidance" in the AMDA practice guideline "is material to a determination whether failure to notify a physician of a specific blood sugar level . . . actually put a resident at any risk of harm"); P. Ex. 32, at 6 (expressing the same thought). That contention assumes that the parameter established by Resident 10's physician (requiring staff to report *any* blood glucose test result of 300 or more) was not calculated to benefit or avoid harm to Resident 10 given her overall health status and other relevant circumstances. Petitioner's declarations provide no foundation for such an assumption, as Petitioner's experts failed to discuss Resident 10's clinical circumstances. The assumption also fails to account for statements by the AMDA and ADA emphasizing the need to manage a patient's diabetes based on individualized treatment goals and care planning.

¹⁷ The declarations of Petitioner's experts indicate that Petitioner was cited for failing to "immediately report" Resident 10's abnormal blood glucose levels, implying that its staff reported those levels to the physician, if not immediately, then reasonably promptly. P. Ex. 30, at 2 (stating an "understanding" that nurses "did not immediately report high blood sugar test values in strict compliance with physician's reporting orders"); P. Ex. 32, at 2 (identical language). However, we see no evidence that the staff *ever* reported the ten blood glucose test results that surveyors identified as having not been reported in accordance with the physician's order.

In addition to skirting the significance of the hypoglycemia-protocol and physician-notification errors, Petitioner's argument about the relevance of current clinical care standards does not negate the possibility that improperly withholding prescribed insulin might cause the resident's blood glucose to rise above the target blood glucose range of 100-200 suggested by the AMDA and ADA.¹⁸ Although Petitioner's medical experts implied that a hyperglycemic episode of that severity would be counteracted by later scheduled insulin doses (*see, e.g.*, P. Ex. 30, at 6), they did not back up Petitioner's claim that "transient" hyperglycemia occurring in the interim poses no risk of, or "potential" for, harm. They merely commented that "isolated blood sugar test results" above the AMDA's suggested target range of 100-200 are "not *necessarily* problematic" (italics added). P. Ex. 30, at 6; P. Ex. 32, at 6. That blood glucose levels exceeding 200 are not "necessarily" problematic means that they could be in some circumstances, a condition consistent with a potential for more than minimal harm.

Petitioner makes various other points to bolster its position that residents were at no risk of harm, but they are unsubstantiated or otherwise fail to identify a genuine dispute of material fact. Petitioner alleges that residents' medical practitioners were in its facility "every day," and that in virtually every cited instance of nursing error, a practitioner visited with the affected resident "within a day or two" and, if necessary, changed the resident's insulin management order. RR at 7-12. Petitioner submits that these facts support an inference that its nursing staff engaged in "ongoing consultation" about the residents' "blood sugar issues" and that such consultation eliminated any potential for significant harm. *Id.* at 2, 7-8, 12, 23, 29.

This thesis has several problems. First, Petitioner presses it only with respect to the nursing lapses involving Resident 10.¹⁹ *See* RR at 22-35. Second, the record does not corroborate Petitioner's allegation regarding the timing of the alleged follow-up visits or actions. In eight of the 14 instances in which the nursing staff failed to report a 300-or-above blood glucose level or implement the Hypoglycemia Protocol for Resident 10, the supposed follow-up action by the physician or nurse practitioner (either a visit with the resident, or the issuance of diabetes management order) did not occur until three to 10 days later, as Petitioner's own timeline shows. *See* RR at 25-29. Third, although Petitioner's medical experts asserted their "understand[ing]" that the nursing staff's errors were followed up with actions (in-person assessments, order changes, etc.) by the

¹⁸ The record shows at least one example of that occurrence: five hours after the nursing staff withheld Resident 75's 6:00 a.m. insulin on February 17, 2016, the resident's blood glucose was 311. CMS Ex. 15G at 11.

¹⁹ Petitioner asserts that a physician saw Resident 37 "frequently" and "consistently wrote that her condition was stable," and that a physician and nurse practitioner periodically visited Resident 75 between February and April 2016. RR at 30 (citing P. Ex. 11) and 35 (citing P. Exs. 26-27). However, Petitioner does not contend that these visits occurred soon after the nursing errors affecting those residents, or that any prompt follow-up visit involved an adjustment to, or consultation about, the resident's diabetes care regimen.

residents' medical practitioners, they expressed no opinion about whether those follow-up actions eliminated any potential for harm. CMS Ex. 30, at 2; CMS Ex. 32, at 2. Fourth, there is no evidence suggesting that any follow-up action occurred because the facility became aware of the errors and acted on them, or because staff had taken quality control measures to prevent or to catch and respond quickly to nursing errors. Under the circumstances, we do not find the proposed inference to be one that any reasonable trier of fact could draw.

Petitioner suggests that “many” of the cited nursing care errors do not constitute “improper care” under the AMDA clinical practice guideline and ADA position statement and thus do not violate section 483.25. RR at 7. Petitioner, however, actually identifies only one example for which it claims that proposition is true: it implies that nursing decisions to hold insulin when a resident’s blood glucose was “low normal” is consistent with AMDA and ADA’s view that “overly aggressive control of asymptomatic high blood sugar” poses a risk of hypoglycemia. RR at 20-21. But Petitioner offered no evidence that any resident was subjected to “overly aggressive” insulin therapy during the relevant period (September 2015 through May 2016). Nor does Petitioner point to any evidence that its nurses’ actions were in fact motivated by their understanding of particular recommendations in the AMDA and ADA publications, or even that its nurses were aware of those publications. Furthermore, the AMDA and ADA publications do not remotely suggest that withholding prescribed insulin without first consulting with the prescribing practitioner (and without even notifying the practitioner promptly afterward), or that failing to implement a hypoglycemia protocol in circumstances calling for its implementation, ever constitutes proper nursing care.

Petitioner also asserts that Dr. Lesesne’s medical opinions lack “any foundation” other than his medical license. RR at 36. We do not agree. Dr. Lesesne holds board certifications in internal medicine, geriatric medicine, and hospice and palliative medicine. CMS Ex. 29, ¶ 6. He also holds a Certified Medical Director credential issued by the AMDA. *Id.* In addition, he has had multiple academic and clinical appointments throughout his career and has “treated many patients with diabetes, including patients who are geriatric or elderly, in general hospital settings, outpatient clinics, and long-term care nursing homes.” *Id.* ¶¶ 5-13. Dr. Lesesne also stated that his opinions reflect his review of clinical records of the five residents whose care was reviewed during the May 2016 survey. *Id.* ¶ 16. Dr. Lesesne’s education, specialty certifications, clinical experience, and familiarity with the residents’ care in Petitioner’s facility provide more-than-adequate foundation for his opinions.

Petitioner asserts that CMS’s evidence fails to show that the cited nursing lapses resulted in actual harm to residents. *See, e.g.*, RR at 17 (“[T]he Statement of Deficiencies does not allege that any resident suffered any injury or adverse outcome resulting from these errors[.]”), 31 (stating there was “no evidence of any impact one way or the other from

holding morning insulin on occasions when [Resident 37's] blood sugar was in the 'low normal' range"), and 33 (asserting the Resident 71's chart indicates that the transcription error which resulted in the resident not receiving an evening insulin dose for one week "caused no change at all in the Resident's average blood sugar ranges, or any measured peaks and valleys, during the material period, and no effect at all on the Resident's presentation, demeanor or level of function"). However, proof that a deficiency resulted in actual harm is unnecessary; CMS need only show that a deficiency created a "potential" to cause more than minimal harm in order to find a SNF out of substantial compliance. *Lakeport Skilled Nursing Ctr.*, DAB No. 2435, at 5 (2012).

To summarize, CMS offered evidence of facts establishing that Petitioner was not in substantial compliance with 42 C.F.R. § 483.25 in its care of five residents with diabetes from September 15, 2015 through May 12, 2016. The record discloses no genuine factual disputes material to resolving the compliance issue presented by CMS. We therefore conclude that CMS is entitled to summary judgment that Petitioner was not in substantial compliance with section 483.25 from September 15, 2015 through May 12, 2016.

B. Summary judgment is inappropriate on the immediate-jeopardy issue.

Having concluded that Petitioner was not in substantial compliance with 42 C.F.R. § 483.25, we next consider CMS's determination that the noncompliance placed residents in immediate jeopardy. Immediate jeopardy is defined as a "situation in which the [SNF's] noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301 (italics added). The Board has said that the term "likely" means "probably" and "reasonably to be expected," and that the term "suggest[s] a greater degree of probability that a particular event will occur than the terms 'possible' or 'potential.'" *Daughters of Miriam Ctr.*, DAB No. 2067, at 10 (2007). Determining whether a deficiency is likely to cause serious harm often entails the application of professional medical or nursing judgment or expertise. *Id.* at 15. An immediate-jeopardy finding must be upheld unless it is "clearly erroneous." 42 C.F.R. § 498.60(c)(2).

Upholding an immediate-jeopardy finding on summary judgment is inappropriate if the facts upon which CMS relied in assessing whether the SNF's noncompliance caused, or was likely to cause, serious harm have been reasonably called into question. *Innsbruck HealthCare Ctr.*, DAB No. 1948, at 8 (2004) (stating that "it is material to evaluating the immediate jeopardy determination to consider the factual underpinnings on which the surveyors relied to apply their expertise"); *Franklin Care Ctr.*, DAB No. 2869, at 9 (2018) (stating that a reviewer "cannot properly evaluate" whether an immediate-jeopardy finding is clearly erroneous "without first resolving material disputes of fact as

to what the facts were and whether they were different than those to which the surveyors (or here, also CMS's expert witness) applied their expert judgment"). Because medical or nursing judgment may inform CMS's assessment of a deficiency's potential impact on residents' well-being, expert opinion proffered by the SNF on that topic may suffice, in appropriate circumstances, to create a genuine factual dispute precluding summary judgment. *Innsbruck* at 8 (holding that a proffer of expert testimony by the SNF created a "genuine dispute of fact over the assessment of the degree of risk [of harm] to the residents" from the SNF's noncompliance).

We make two preliminary observations before discussing the evidence relevant to the immediate-jeopardy issue. First, in its motion for summary judgment, CMS acknowledged its need to show the absence of any factual dispute material to resolving that issue. MSJ at 3. However, CMS did not proceed to explain, or clearly explain, why it met that obligation. Instead, CMS emphasized that Petitioner had not "rebutted" CMS's "prima facie case," wrongly implying that the immediate-jeopardy finding could be sustained because the weight of the evidence supported it. *Id.* at 1-2, 9-12. Second, CMS's appeal brief reflects a misunderstanding of the applicable appellate review standard, compromising the persuasiveness of its argument on the immediate-jeopardy issue. The brief indicates that our review of the ALJ's decision is confined to deciding whether that decision is supported by "substantial evidence." *See* CMS Response Br. at 2, 19 (stating that the immediate jeopardy finding is supported by substantial evidence). In fact, our review of the grant of summary judgment is *de novo*, which means that we must initially decide whether CMS, as the moving party, demonstrated the absence of a genuine dispute of material fact. CMS does not assert (in its appeal brief) that it made that demonstration; it merely reiterates that Petitioner failed to "adequately rebut" the "allegations of actual and potential harm." *Id.* at 22-23.

According to CMS's summary judgment motion, the immediate-jeopardy determination is founded on opinions expressed by Dr. Lesesne and Nurse Pollard-Ray in their declarations. MSJ at 7; CMS Ex. 28, ¶¶ 11, 38 (indicating that Nurse Pollard-Ray concurred with the state survey agency's finding that the noncompliance was at the immediate-jeopardy level). On their face, however, these declarations create some uncertainty about whether CMS's experts thought that the cited nursing errors had caused serious harm or were likely to cause such harm (if not corrected). Dr. Lesesne stated at the outset of his declaration that he had been asked to address whether any noncompliance by Petitioner "result[ed] in the *potential* for serious bodily harm and/or death." CMS Ex. 29, ¶ 15 (italics added). He went on to say that residents were "*at risk* of serious harm as a result of the deficient diabetes management practices." *Id.*, ¶ 39 (italics added). His opinions about specific nursing errors almost invariably used the words "at risk of serious harm" (or comparable phraseology) to characterize the errors' potential impact on residents. *Id.*, ¶¶ 40-41, 45-47, 49, 60, 62, 69. However, to warrant

an immediate-jeopardy finding, a deficiency must have done more than create a “potential” for (or possibility of) serious harm or death; it must have either “caused” actual serious harm, impairment, or death, or have been “likely to cause” that result. *Franklin Care Ctr.* at 9. A “mere risk” or possibility of harm is not equivalent to a likelihood of that outcome. *Innsbruck* at 5. Dr. Lesesne did say that Petitioner’s errors had caused “actual harm” to Residents 71 and 10 but did not state explicitly that the harm resulting from those errors was “serious” given the residents’ clinical circumstances. CMS Ex. 29, ¶ 40.

As Dr. Lesesne did, Nurse Pollard-Ray repeatedly stated that the residents whose nursing care was reviewed by surveyors were “at risk” of harm from Petitioner’s noncompliance without further characterizing or quantifying the level of risk or probability that the noncompliance would cause serious harm. CMS Ex. 28, ¶¶ 39A (failure to implement Hypoglycemia Protocol put residents “at risk of serious bodily harm”), ¶ 39B (all residents were “at risk” of serious harm “because nursing staff incorrectly believed that they were authorized to disregard physician orders”), ¶ 39E (failure to arrange hemoglobin test put resident “at risk of serious bodily harm”), and ¶ 39F (all residents were “at risk of being subjected to . . . deficient practices which carried the risk of serious bodily harm or death”).²⁰ Nurse Pollard-Ray also testified that the risk of serious harm to Residents 71, 37, and 10 was, in her opinion, “immediate” (*id.*, ¶ 40), implying that serious harm was soon-to-occur as a direct result of the cited nursing errors. However, CMS appears to concede that Petitioner’s expert opinions sufficed to raise a genuine dispute about whether its nursing errors created an “immediate” risk of serious harm or death.²¹ CMS Response Br. at 23-24 (citing the testimony by Drs. Levenson and Pandya that “none of the errors was of the sort that was likely to cause serious harm” and stating that Petitioner had “[a]t most . . . offered opinions that the facility’s failures did not cause immediate harm or the potential for immediate harm or death by a specific act or failure to act alleged in the Statement of Deficiencies”).

²⁰ Like the declarations of its expert witnesses, CMS’s appeal brief discusses the immediate-jeopardy issue using phraseology that does not match the regulatory definition of immediate jeopardy – stating, for example, that Petitioner’s noncompliance had “caused actual harm” (but not actual “serious” harm), “posed serious harm” (omitting to mention the requirement that a specific regulatory violation be “likely to cause” such harm), “resulted in the potential for harm” (without characterizing the risk of harm as a likelihood or the harm as serious), and created an “inherent potential for immediate harm.” Response Br. at 1, 2, 23.

²¹ In its motion for summary judgment, CMS asserted that “[n]one of Petitioner’s experts reviewed the relevant records in this case” and as a result their opinions are “not credible” because they lack “adequate foundation.” MSJ at 1, 10-12. CMS does not press that contention in this appeal. Moreover, Petitioner’s experts stated they were “asked to review” the Statement of Deficiencies and some or all of the case record. P. Ex. 30, at 2; P. Ex. 32, at 1. A finder of fact could reasonably infer from these statements that Petitioner’s experts did as they were asked to do and based their opinions on a review of relevant medical and nursing records.

Furthermore, by CMS’s own reckoning (and the ALJ’s as well), the validity of the immediate-jeopardy finding hinges on what CMS calls the “systemic” nature of Petitioner’s deficient diabetes care practices.²² CMS Ex. 28, ¶¶ 15, 39B, 39F; CMS Response Br. at 23-24 (asserting that Petitioner “cannot establish [that] the immediate jeopardy determination was clearly erroneous because it [has] simply never addressed CMS’ allegation that the systemic problems with diabetes management, in and of itself, resulted in the potential for harm to the five residents at issue as well as all diabetic residents in the facility”); ALJ Decision at 7 (stating that “[t]he crux of CMS’s case” was the alleged “systemic failure” by Petitioner to “provide prescribed care to diabetic residents”). Nurse Pollard-Ray testified that “systemic deficiency practices” – in particular, the “pattern of nursing staff disregarding physician orders for insulin administration” – put all of Petitioner’s residents with diabetes “at risk of hyperglycemia . . . because of the arbitrariness of when the nurses decided to hold the insulin (i.e., there was a risk it could be incorrectly held at a time when administration of the insulin was critical).” CMS Ex. 28, ¶¶ 15, 39B, 40B (italics added). However, survey interviews of LPN5, RN51, and RN53 provide evidence from which a reasonable trier of fact could infer that, while the nursing staff’s unilateral decisions to hold residents’ morning doses of insulin violated nursing practice standards, those decisions were not arbitrary but based on concern that administering the prescribed doses might trigger hypoglycemia. In addition, Petitioner’s experts testified that nurses’ decisions to withhold insulin appeared to be “consistent with trying to protect the subject residents from harm due to overtreatment,” and that later scheduled doses would have treated any hyperglycemia resulting from the missed doses. P. Ex. 30, at 4, 6; P. Ex. 32, at 4, 6-7. CMS also failed to point to a single example of insulin being withheld at a clinically “critical” time.

Nurse Pollard-Ray also characterized the failures to implement the Hypoglycemia Protocol as “systemic.” As we said, however, CMS conceded that Petitioner’s medical experts had offered opinions sufficient to create a genuine dispute of material fact about whether the protocol-implementation failures were likely to cause serious harm, and Nurse Pollard-Ray offered no further explanation of how their allegedly “systemic” nature created the likelihood of serious harm to residents (as opposed to a lower level of risk to one or more residents). Based on the evidence (and gaps in evidence) we have just

²² CMS’s use of the term “systemic” is somewhat inapt in this context. To call a deficiency “systemic” is to characterize its scope – that is, whether it was “isolated,” constituted a “pattern,” or was “widespread.” See 42 C.F.R. § 488.404(b); *Cross Creek Health Care Ctr.*, DAB No. 1665, at 22-23 (1996) (discussing the determination of a deficiency’s scope under the survey-and-enforcement scheme applicable to SNFs and noting that “‘widespread’ scope may be identified if a systemic failure has affected or could affect a large number of residents across the facility and is therefore considered pervasive”). Whether a “systemic” deficiency warrants an immediate-jeopardy finding (that is, a finding about the deficiency’s severity) depends not on the deficiency’s scope but on whether it actually caused, or was likely to cause, serious harm.

described, a trier of fact could reasonably conclude that an immediate-jeopardy finding based on the “systemic-noncompliance” rationale articulated by Nurse Pollard-Ray alone would not necessarily survive the clearly erroneous standard. Therefore, summary judgment on this issue was premature.

CMS contends (Response Br. at 23) that the ALJ correctly sustained the immediate-jeopardy finding based on the following reasoning:

[T]he immediate jeopardy at Petitioner’s facility wasn’t confined solely to those diabetic residents who were put in harm’s way. What is evident from this noncompliance was that Petitioner’s staff demonstrated either a persistent inability to comply with physicians’ orders or an unwillingness to do so. That also is immediate jeopardy because it establishes that the staff put all residents at risk, whether or not they suffered from diabetes.

ALJ Decision at 4. In this passage the ALJ inferred that because Petitioner’s nurses disregarded diabetes management orders (withholding prescribed insulin and failing to report abnormal blood glucose levels), they likely disregarded, or failed to consistently follow, orders for other types of treatment and care. That adverse inference,²³ even if it could reasonably be drawn, cannot be the basis for granting summary judgment against Petitioner because, at the summary judgment stage, the ALJ may draw only reasonable inferences *favorable* to the non-movant. CMS does not point to any undisputed evidence that Petitioner’s nurses consciously, willingly, or routinely disregarded or failed to carry out medical practitioners’ orders in areas besides diabetes care. Absent such evidence, a trier of fact could reasonably conclude that the nursing staff’s failures to carry out medical practitioner orders were confined to the circumstances specified in the SOD.

Another reason for questioning the propriety of summary judgment in this aspect of the case is that CMS’s immediate-jeopardy determination appears to have been based on factual premises that are not the same as those found to be undisputed by the ALJ, and therefore disputes of material fact reflected in the divergent premises must be resolved before immediate jeopardy can be assessed. *See, e.g., Innsbruck*, DAB No. 1948, at 8; *Franklin*, DAB No. 2869, at 9. In this case, only those facts which are undisputed and reasonable inferences favoring the non-movant may be considered to be the facts found by the ALJ. As we have explained, even if Petitioner is given the benefit of all favorable reasonable inferences, the undisputed facts that we have identified (in the previous section) are sufficient to establish that Petitioner’s deficiency created a potential for more than minimal harm. Those facts, however, are not coextensive with the allegations in the

²³ That inference goes well beyond the opinions expressed by Nurse Pollard-Ray. She testified that “systemic practices regarding diabetes management” put only “diabetic residents” at “immediate risk of harm”; she did not say that the practices were likely to cause serious harm to residents receiving care for conditions other than diabetes. CMS Ex. 28, ¶ 40.

SOD or CMS's motion for summary judgment. Therefore, in order to sustain the grant of summary judgment on the immediate-jeopardy issue, we would need to be able to discern whether the immediate-jeopardy determination could be found not clearly erroneous even if based only on the undisputed facts we have identified. To do so, we review the motion for summary judgment to ascertain the factual basis for finding a likelihood of serious harm or actual serious harm.

As detailed above, CMS's summary judgment motion failed to apply, or clearly apply, the standard for summary judgment (focusing on whether its prima facie case was rebutted rather than on identifying undisputed facts) and at times also incorrectly framed the standard for immediate jeopardy (referring, as did its experts' statements, to whether a risk was serious or immediate in time rather than whether it was likely). *See, e.g.*, MSJ at 8, 9; *but see id.* at 21, citing 42 C.F.R. § 488.301 (correctly noting, based on the regulatory language, that immediate jeopardy requires "a likelihood of serious injury or impairment based on the cited noncompliance"). As a result of the ambiguous language used by CMS, it is not entirely clear which specific facts formed the basis for CMS's immediate-jeopardy determination, or, put another way, whether that determination would have been made based solely on the facts and inferences which we have found to support summary judgment on the issue of whether Petitioner was out of substantial compliance. *See, e.g.*, MSJ at 12-13 (Petitioner "fail[ed] to address all of the particular harm and particular potential for harm caused by Petitioner's noncompliance"). For example, CMS asserted that Petitioner's nursing staff's "cavalier attitude toward following physician orders and facility protocol" was likely to cause death or serious harm to the residents. MSJ at 15 (citing CMS Ex. 29, at 10 ¶¶ 44-46, 13 ¶ 60, 14 ¶ 64, and 15 ¶ 69). We have found it undisputed that the nurses at times failed to follow physician orders and facility protocol. However, Petitioner presented or pointed to evidence which could permit an ALJ to draw a reasonable inference that the nurses' actions were not based on a "cavalier attitude." Instead, an ALJ might infer that the nurses acted based on beliefs that administering insulin at the scheduled hour would endanger patients with low blood glucose readings, on a misunderstanding of their flexibility or authority to alter the dosage, and on good faith errors. CMS Ex. 1B at 8; P. Ex. 30 (Levenson Decl.) at 4. It is unclear whether the finding of a "cavalier attitude" was a material component of the immediate-jeopardy determination. In addition, CMS's summary judgment motion did not take a clear position on whether certain facts and evidence highlighted by Petitioner called into question the premises of the immediate-jeopardy finding. For example, CMS discounts Petitioner's evidence regarding the frequency of physician or nurse practitioner visits and chart reviews of the residents at issue, pointing out that, even if true, it would not make the nurses' failures "excusable." MSJ at 18-19. As we have already said, we agree that, as a matter of law, follow-up visits or reviews do not make the noncompliance somehow excusable. But that does not establish as undisputed fact that the evidence of regular visits did not mitigate the likelihood of serious harm occurring as a result or preclude a reasonable inference that the regular visits did so.

In summary, CMS’s primary rationale for seeking summary judgment in favor of its immediate-jeopardy determination – the alleged “systemic” nature of Petitioner’s noncompliance – rests on disputed facts or inferences (particularly the finding that nurses “arbitrarily” withheld insulin); CMS’s experts were unclear in their declaration about whether they thought the nursing care deficiencies cited by the surveyors had caused, or were likely to cause, serious harm; and Petitioner proffered expert testimony that CMS evidently regards as adequate to create a genuine dispute about whether the cited nursing errors involving Residents 75, 71, 55, 37, and 10 were likely to cause serious harm under the circumstances. We conclude that summary judgment on the immediate-jeopardy issue is inappropriate in these circumstances. We of course take no position on the persuasiveness or credibility of the parties’ expert opinions, the weight to be accorded to each side’s evidence, or the relative strength of any competing factual inferences – and we “in no way impl[y] that [Petitioner] has demonstrated that the [immediate-jeopardy] determination was wrong, much less clearly erroneous.” *Franklin Care Ctr.* at 14. We merely hold that a trier of fact cannot, at this stage, determine whether the immediate-jeopardy determination is clearly erroneous without affording Petitioner an opportunity for a hearing and resolving factual disputes, apparent on the record, that bear upon that determination’s validity.

V. CONCLUSION

For the reasons stated in part A of our Analysis, we affirm the ALJ’s conclusion that Petitioner was not in substantial compliance with 42 C.F.R. § 483.25 from September 15, 2015 through May 12, 2016. For the reasons stated in part B of our Analysis, we vacate the grant of summary judgment to CMS on the immediate-jeopardy issue and remand the case to the ALJ for further proceedings.

/s/

Constance B. Tobias

/s/

Susan S. Yim

/s/

Leslie A. Sussan
Presiding Board Member

Appendix A

Appendix A is available here:

https://web.archive.org/web/20130919115822/https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_p_ltcf.pdf