Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Golden Living Center – Superior
Docket No. A-16-44
Decision No. 2768
February 3, 2017

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Golden Living Center – Superior (Golden), a Wisconsin skilled nursing facility (SNF), has appealed the January 28, 2016 decision by an administrative law judge (ALJ*), Golden Living Center – Superior*, DAB CR4514 (2016) (ALJ Decision). The chief issue before the ALJ was whether Golden was in substantial compliance with 42 C.F.R. § 483.65, which requires a SNF to adopt and implement infection control policies, during late January and early February 2015.[1] Granting summary judgment to the Centers for Medicare & Medicaid Services (CMS), the ALJ held that Golden was not in substantial compliance with section 485.65 beginning on January 26, 2015 and that this noncompliance was at the immediate-jeopardy level of severity from January 26 through February 9, 2015. In addition, the ALJ sustained, as reasonable, the civil money penalty (CMP) imposed by CMS for that noncompliance.

We find no error in the ALJ's decision. Accordingly, we affirm the grant of summary judgment to CMS on all issues.

Legal Background

To participate in the Medicare program, a SNF must be in "substantial compliance" with the participation requirements in 42 C.F.R. Part 483, subpart B. 42 C.F.R. § 483.1. The term "noncompliance," as used in the applicable regulations, is synonymous with lack of substantial compliance. *Id.* § 488.301 (defining "noncompliance").

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[1] On October 4, 2016, CMS issued a final rule that amended 42 C.F.R. § 483.65 (and other Medicare requirements for long-term care facilities) and re-designated it as 42 C.F.R. § 483.80. *See* Final Rule, *Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities*, 81 Fed. Reg. 68,688, 68,807 (Oct. 4, 2016). Our analysis and decision is based on section 483.65 as it existed in February 2015, the month in which the state of Wisconsin performed the compliance survey providing the bases for CMS's determination of noncompliance. *See Carmel Convalescent Hospital*, DAB No. 1584, at 2, n.2 (1996) (applying regulations in effect on the date of the survey and resurvey).

Compliance with the Part 483 requirements is verified through onsite surveys performed by state health agencies. *Id.* § 488.10(a), 488.11. A state survey agency reports any "deficiency" (failure to meet a participation requirement) it finds in a Statement of Deficiencies. *Id.* §§ 488.301, 488.325(f)(1).

CMS may impose enforcement "remedies," including CMPs, on a SNF that is 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(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 "actual 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." *See id.* § 488.438(a) (authorizing the highest CMPs for immediate-jeopardy-level noncompliance); *Woodland Oaks Healthcare Facility*, DAB No. 2355, at 2 (2010) (citing authorities).

Case and Procedural Background

The Wisconsin Department of Health Services (WDHS) performed a compliance survey of Golden in February 2015. CMS Ex. 1. As a result of that survey, WDHS cited Golden for multiple deficiencies, the most serious being a violation of section 483.65, which states (in part) that a SNF "must establish and maintain an infection control program . . . ." *Id.* at 1. The basis for that deficiency citation, as outlined in WDHS's Statement of Deficiencies, was a finding that Golden had failed to "take immediate preventive measures [in January 2015] when acute respiratory illness (ARI) symptoms were discovered within the Alzheimer Care Unit (ACU) or when the facility had a confirmed case of influenza A . . . on that same ACU." *Id.* at 32-33. WDHS further found that Golden's violation of section 483.65 had placed residents in immediate jeopardy from January 26 through February 9, 2015. *Id.* at 35, 60.

WDHS revisited Golden in late March 2015 and determined that Golden was back in substantial compliance with all Medicare (Part 483) requirements as of March 12, 2015. *Id.* at 71.

CMS concurred with WDHS's survey findings and imposed a $5,100 per-day CMP for the immediate-jeopardy period (January 26 through February 9, 2015) and a $450 per-day CMP for the remaining period of noncompliance (February 10 through March 11, 2015). CMS Ex. 2, at 1-3, 9-10.

Golden then requested an ALJ hearing, asserting that there was "no factual or legal basis for the findings of noncompliance and 'immediate jeopardy' relating to infection control issues" or "for the [$5,100 per-day] CMP imposed as the result of those findings." May 29, 2015 Request for Hearing at 2. Golden stated that it was not appealing any deficiency citation other than the finding of noncompliance with section 483.65. *Id.* at 2 (stating that "[Golden] does *not* appeal the 'non-jeopardy' deficiencies" or the "$450 per day CMP imposed for those deficiencies" (italics in original)).

After the parties exchanged evidence about the issues raised in Golden's hearing request, CMS moved for summary judgment.[2] CMS generally contended that Golden was noncompliant with section 483.65 because it "failed to follow" its infection control policies during a January 2015 influenza outbreak in its Alzheimer's Care Unit (ACU). *See* CMS's Dec. 1, 2015 Mem. in Support of Motion for Summary Judgment (MSJ) at 14-20. More specifically, CMS alleged that Golden:

- did not promptly administer Tamiflu, an antiviral medication, to non-ill ACU residents as a "prophylactic" measure to prevent the spread of infection (MSJ at 15-19, 20);

- allowed staff to move between the ACU and other parts of the facility "a dozen times" (MSJ at 19, 20); and

- allowed ACU residents to continue to participate in small group activities after the influenza outbreak (MSJ at 19, 20).

CMS also contended that its immediate-jeopardy finding was not clearly erroneous because there was "no genuine dispute that a failure to effectively implement infection control policies was likely to cause serious injury or death to a resident." MSJ at 21-22. In addition, CMS contended that "undisputed evidence . . . easily supports" its finding as to the duration of the immediate-jeopardy period. *Id.* at 22. Finally, CMS urged the ALJ to sustain the "upper-range CMP" imposed for the immediate-jeopardy period, noting that Golden had proffered "no evidence or argument to contest the [penalty's] reasonableness . . . ." *Id.* at 22-24.

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[2] In conjunction with its motion for summary judgment, CMS asked the ALJ to stay the proceeding before him. *See* Dec. 1, 2015 Motion to Stay Proceedings, C-15-2887. The ALJ neither granted nor denied the stay request but issued his decision less than two months later. Golden now asserts that the ALJ's failure to deny the stay somehow created a "significant – and unnecessary – due process issue" due to CMS's "practice of seizing and 'escrowing' (without interest) civil money penalties pending administrative appeals." RR at 10, n.4. However, Golden does not explain how its due process rights (that is, its rights to notice and an opportunity to be heard) were impaired in this administrative appeal process. If Golden is alleging that CMS unlawfully escrowed its funds, we have no authority to rule on the merits of that claim (or give Golden a remedy) in this proceeding under 42 C.F.R. Part 498. *See Park Manor Nursing Home*, DAB No. 2005, at 4-5 (2005) (discussing the types of determinations appealable to administrative law judges and the Board under 42 C.F.R. Part 498).

In a brief opposing CMS's summary judgment motion, Golden contended that the evidence shows that its staff "*did* follow not only its own influenza protocols . . . but . . . all pertinent CDC [Centers for Disease Control and Prevention] and State Guidelines, as interpreted and applied by its Medical Director." Pet.'s Dec. 8, 2015 Reply to CMS's Motion for Summary Judgment ("Opp. to MSJ") at 3. Golden also argued that a SNF's failure to comply with a requirement in an internal infection control policy does not violate section 483.65 unless the regulation itself imposes that requirement, either expressly or by incorporation:

> . . . Section 483.65 does not dictate the specific content of any facility clinical policy, and so CMS cannot simply assert that one or another provision of such a policy ipso facto establishes the *regulatory* standard – much less one enforceable by summary judgment – without showing how the regulation imposes such a requirement, for instance, via incorporation of a clinical standard established by some CDC or some other standard-setting body. Likewise, where a regulation such as Section 483.65 does not specify the contents of a facility's clinical policies, CMS cannot demonstrate a regulatory violation simply by alleging a violation of one provision of a facility policy without offering evidence that the provision in question is necessary to comply with the regulation.

Id. at 4 (italics in original).

<u>ALJ Decision</u>

The ALJ held that "the facts as asserted by CMS" are undisputed and "plainly establish" that Golden did not comply with its "own protocols" for responding to an influenza outbreak in its ACU in late January 2015. ALJ Decision at 3, 4, 5, 8 (stating that Golden "admit[ted] or fail[ed] to rebut the facts that CMS asserts are undisputed"). In particular, said the ALJ, CMS's facts establish that Golden did not implement (or timely implement) internal protocols calling for: (1) the administration of prophylactic antiviral medication (Tamiflu) "within 48 hours of the *first* diagnosis of influenza"; (2) restriction of staff movement to and from the ACU; and (3) suspension of group activities during the outbreak. *Id.* Golden's failure to follow its established protocols, the ALJ held, violated 42 C.F.R. § 483.65:

> The regulation [section 483.65] does not contain specific protocols for dealing with influenza outbreaks. Rather, it imposes on skilled nursing facilities the duty to develop their own protocols and, importantly, to maintain them. Here, there is no question that [Golden] developed detailed

> protocols for addressing an influenza outbreak. But, the facts offered by CMS show that [Golden] failed to implement those protocols at the critical moment when an outbreak occurred. That is noncompliance with the regulation' s requirement that a facility maintain its infection controls.

Id. at 4. The ALJ rejected Golden's argument that it did not violate section 483.65 because that regulation does not articulate standards for influenza control:

> [Golden] repeatedly points out that 42 C.F.R. § 483.65 fails to identify specific infection control requirements applicable to influenza outbreaks. [Golden] asserts additionally that CMS has not at any time identified an objective standard that defines the necessary elements of influenza control. Thus, according to [Golden], CMS's entire case collapses because CMS has not and cannot identify any criteria pursuant to which [Golden] may be held accountable. . . .
>
> This argument is a red herring. CMS did not identify a binding and objective standard for influenza control because the regulation governing infection control at skilled nursing facilities is not predicated on inflexible and rigid standards. Instead, the regulation vests responsibility in skilled nursing facilities to develop their own standards and protocols consistent with professionally recognized standards of nursing care. That is evident from the plain language of 42 C.F.R. § 483.65. Moreover, the regulation takes into account the likelihood that professional standards of care will evolve with time. Putting a specific objective requirement in the regulations undercuts the statutory purpose of assuring that skilled nursing facilities have the flexibility to adapt their protocols to changed circumstances.
>
> A skilled nursing facility is granted discretion to develop and implement infection control protocols including those that deal with influenza outbreaks. Once those protocols are in place a facility is required to maintain them – that is to say, it is required to implement its protocols and to assure that they are working.

Id. at 5-6 (citations omitted). The ALJ rejected various other arguments made by Golden concerning CMS's noncompliance determination, some of which Golden reiterates here and we address below. *Id.* at 4-9. Finally, the ALJ sustained CMS's immediate-jeopardy finding as well as the $5,100 per day CMP imposed by CMS.[3] *Id.* at 9-10.

<u>Standard of Review</u>

We review de novo an ALJ's decision to grant summary judgment. *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 applicable substantive law will identify which facts are material, and only disputes over facts that might affect the outcome of the [case] under the governing law will properly preclude the entry of summary judgment." *Id.* (internal quotation marks omitted). In deciding whether there is a genuine dispute of material fact, 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).

We also "view the evidence presented through the prism of the substantive evidentiary burden." *Anderson v. Liberty Lobby*, 477 U.S. 247 at 254-55 (1986). Under the substantive law, CMS has the initial burden to make a prima facie case. *Oaks of Mid City Nursing & Rehab. Ctr.* DAB No. 2375, at 6 (2011). "To make a prima facie case, CMS must com[e] forward with evidence related to disputed findings that is sufficient (together with any undisputed findings and relevant legal authority) to support a decision in its favor absent an effective rebuttal." *Id.* (internal quotation marks omitted). "Once CMS has made a prima facie showing of noncompliance, however, the SNF must carry its ultimate burden of persuasion by showing, by a preponderance of the evidence, on the record as a whole, that it was in substantial compliance during the relevant period." *Id.* (internal quotation marks omitted).

Hence, in deciding whether a SNF has defeated an adequately supported motion for summary judgment – a motion that identifies facts sufficient to make out a prima facie case – we consider whether a rational trier of fact, viewing the entire record in the light most favorable to the SNF, and drawing all reasonable inferences in its favor, could find its presentation sufficient to carry its burden of persuasion (to show substantial compliance). *Dumas Nursing & Rehab., L.P.*, DAB No. 2347, at 6 (2010) (stating that, on summary judgment, "it is appropriate for the tribunal to consider whether a rational

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[3] The ALJ also concluded that CMS's lower-level (non-immediate jeopardy) noncompliance findings, along with the remedies imposed for the period of noncompliance from February 10 through March 11, 2015, were uncontested and thus "administratively final" actions. ALJ Decision at 1, n.1. Golden takes no issue with that conclusion in this appeal.

trier of fact could regard the parties' presentations as sufficient to meet their evidentiary burdens under the relevant substantive law"). Where the evaluation of credibility or weighing of competing evidence is required to decide whether the SNF has demonstrated substantial compliance, however, summary judgment is not appropriate. *See, e.g., Kingsville Nursing & Rehab. Ctr.*, DAB No. 2234, at 8-9 (2009); *Madison Health Care, Inc.*, DAB No. 1927, at 6 (2004).

Discussion

A. *Applicable substantive law*

Title 42 C.F.R. § 483.65 (Oct. 1, 2014) states, in its prefatory paragraph, that a SNF "must establish and maintain an infection control program designed to provide a safe, sanitary and comfortable environment and to help prevent the development and transmission of disease and infection." Section 483.65 further states that an infection control program established by the SNF must be one under which it (1) "[i]nvestigates, controls, and prevents infections in the facility" and (2) "[d]ecides what procedures . . . should be applied to an individual resident[.]" 42 C.F.R. § 483.65(a)(1), (2).

In light of section 483.65's injunction to "establish *and maintain*" (italics added) an infection control program and stated focus on achieving health outcomes (*e.g.*, the prevention of the transmission of disease and infection), the Board has held that section 483.65 requires a SNF to do more than merely adopt such a program as its internal policy; the regulation also requires the SNF to implement the program's prescribed precautions. *Heritage House of Marshall Health & Rehab. Ctr.*, DAB No. 2566, at 12 (2014) (holding that section 483.65 "can only reasonably be interpreted as requiring not just that an infection control policy exist, but also that the policy be followed"); *see also The Windsor House,* DAB No. 1942, at 60 (2004) (stating that section 483.65 "makes clear that it is not enough simply to have an infection control program, but the facility must also follow the precautions established in that program"); *Park Manor Nursing Home* at 60 (stating that section 483.65 "can reasonably be read as requiring the facility to implement an effective infection control program in [its] daily interaction with residents").

The Board applied these principles most recently in *Heritage House*. In that case, the Board affirmed an ALJ's conclusion that a SNF was not in substantial compliance with section 483.65(a) when it failed to follow certain "standard precautions" (wearing a gown to treat a bacterium-infected resident) and "isolation control" procedures (placement of a sign at the entrance to the affected resident's room) specified in the SNF's internal infection control policies. DAB No. 2566, at 12-13.

Consistent with *Heritage House,* the ALJ in this case held, and we concur, that section 483.65 obligated Golden to adopt policies and procedures to minimize the spread of infection (including influenza) and then to implement them. Because CMS does not allege that Golden failed to adopt facially adequate infection control policies and procedures, our review (like the ALJ's) focuses on Golden's alleged failure to "maintain" – that is, implement – them. Accordingly, our review, like the ALJ's, addresses two questions: (1) what measures did Golden's infection control policies call upon its staff to implement in response to an influenza outbreak? and (2) did Golden implement those measures during the influenza outbreak in its ACU in early 2015?[4]

B. *The parties' evidence*

As noted, the parties exchanged evidence prior to CMS moving for summary judgment. That evidence included residents' nursing records (CMS Exs. 23-27), pertinent resident care policies (P. Exs. 1 and 2), and declarations offered as written direct testimony. CMS offered declarations from WDHS surveyors and from a university faculty physician with expertise in geriatric medicine. CMS Exs. 28, 30, 33, 36, 38. Golden offered declarations from, among others, its Director of Nursing (P. Ex. 11), Assistant Director of Nursing and Infection Control Coordinator (P. Ex. 12), Medical Director (P. Ex. 13), and Director of the Alzheimer's Care Unit (P. Ex. 14).

The parties' evidence reveals the following facts, all of which are undisputed.

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[4] Petitioner suggests (and we will assume for the sake of argument) that the state survey agency found it noncompliant with section 483.65 based solely on a finding that it did not meet the state of Wisconsin's infection control standards. *See* RR at 1-2. Petitioner further asserts that CMS has (in this case) ignored or abandoned the survey agency's rationale for the noncompliance determination and sought to justify that determination on a different ground – namely, that it failed to implement its internal infection control policies, which call upon staff to meet and follow CDC standards and practices. *Id.* at 2, 5, 10-11. Petitioner insinuates that it was legally improper for CMS to articulate a rationale for the noncompliance determination that differs from the one advanced by the state survey agency. There was no impropriety. CMS may defend a noncompliance determination based on facts, evidence, or reasoning not specified in the Statement of Deficiencies, provided, of course, that due process requirements – adequate notice and a meaningful opportunity to be heard – are satisfied. *Cf. Northern Montana Care Ctr.*, DAB No. 1930, at 26 (2004) ("CMS's prima facie case is not limited to the findings and statements in the form 2567" (the Statement of Deficiencies)); *Lake Mary Health Care*, DAB No. 2081, at 12 (2007) ("The Board has long rejected the suggestion that all evidence supporting a noncompliance finding must be set out in the [Statement of Deficiencies]."); *Livingston Care Ctr.*, DAB No. 1871, at 20 (2003) (discussing due process), *aff'd, Livingston Care Ctr. v. U.S. Dep't of Health & Human Servs.*, 388 F.3d 168 (6th Cir. 2004). Petitioner was afforded due process in this case: "[t]here was adequate notice . . . because CMS's summary judgment motion clearly advised [Petitioner] of the evidence and allegation[s] supporting its *prima facie* case," and Petitioner "had an opportunity to respond to the summary judgment motion and to proffer rebuttal evidence." DAB No. 1871, at 20.

1. <u>Golden's infection control program</u>

"Influenza is a virus that spreads quickly, especially where people live in close quarters." CMS Ex. 36, ¶ 10. "Influenza is primarily transmitted from person to person via virus-laden droplets that are generated when infected persons cough or sneeze." P. Ex. 2, at 1. Transmission may also occur through direct contact or indirect contact with respiratory secretions such as touching surfaces contaminated with influenza virus and then touching [one's] eyes, nose, or mouth." *Id.*

"An influenza outbreak in a nursing home can be serious because residents are more likely to be hospitalized or die from the illness or its complications as a result of age and weakened immune systems." CMS Ex. 38, ¶ 8; P. Ex. 2, at 1 (stating that "[i]nfluenza is a respiratory disease that can and does cause substantial illness and even death" among long-term care residents). It is therefore "important that a nursing home immediately implement procedures to prevent the spread of influenza once one case has been identified within its walls." CMS Ex. 36, ¶ 10; *see also* CMS Ex. 38, ¶ 8 (stating that a delay in recognizing an influenza outbreak "increases the chances of transmission" of the virus among residents and staff"); P. Ex. 13, at 3 ("I certainly agree that it is important to detect and respond promptly to influenza outbreaks, as the ailment can be dangerous, even deadly, to frail elderly persons."); P. Ex. 2, at 1 ("If you see even one case of influenza in your facility, you have an outbreak and should place outbreak management procedures into place immediately.").

In December 2014, Golden adopted, or updated, written in-house infection control policies, formally called "Guidelines" or "Procedures." *See* P. Ex. 1, at 1, 5, 6, 11, 12, 19, 20, 24; P. Ex. 2, at 4, 7; Pet.'s Request for Review (RR) at 16, 17, n.8 (stating that Golden has a "*series* of pertinent infection control policies and procedures that implement" section 483.65).[5]

Four of Golden's infection control policies contain relevant material: Guideline # IC-801, titled "Infection Control Program"; Guideline # IC-800, titled "Infection Control"; Guideline # CLIN702, titled "Influenza Outbreak Guideline"; and Procedure # INF440, titled "Influenza Outbreak Antiviral Procedures." P. Ex. 1, at 1, 6; P. Ex. 2, at 1, 5.

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[5] Some of the policies incorporate excerpts from CMS's *Guidance to Surveyors for Long Term Care Facilities* (Appendix PP to CMS's State Operations Manual, CMS Pub. 100-07). *Compare* P. Ex. 1 and CMS Ex. 43. Those excerpts describe recommended infection control practices and precautions along with citations to the published sources of those recommendations. CMS Ex. 43.

Guideline #IC-801 states that "[p]olicies and procedures are the foundation of the facility's infection prevention and control program" and "are reviewed periodically and revised as needed to conform to *current standards of practice* or to address specific facility concerns." P. Ex. 1, at 8 (italics added). Guideline # IC-800 identifies the CDC as a source of current standards of practice, stating that "[i]t is important that all infection prevention and control practices reflect current . . . CDC . . . guidelines." *Id.* at 5.

Guideline # CLIN702 – the Influenza Outbreak Guideline – states:

> When is influenza in your facility an outbreak?
>
> If you see even one case of influenza in your facility, you have an outbreak and should place outbreak management procedures into place immediately. . . .

P. Ex. 2, at 1. The guideline further instructs the nursing staff to implement "all" of 25 listed infection control measures "as soon as influenza is suspected" and to "not wait to confirm" an influenza diagnosis before responding to a case of suspected influenza. *Id.* at 3. Those listed infection control measures include:

> Call and inform your Medical Director – request order for prophylactic anti-viral medications for residents according to current recommendations. Consider medicating staff also. . . .
>
> * * *
>
> Do not move your staff around the building. Designated staff should stay on their regulatory scheduled area and should not go from floor to floor. . . .
>
> * * *
>
> Cancel all activities/serve all meals in rooms if several residents have influenza on a particular wing. . . .

Id. at 1-4. The Influenza Outbreak Guideline refers the reader to a CDC "website for professionals" (www.cdc.gov/flu/professionals/index.htm) for additional "[h]elpful and up to date information." *Id.* at 4.

Procedure # INF440 – Influenza Outbreak Antiviral Procedures – informs staff about "[h]ow to obtain [antiviral] medication [Tamiflu or Relenza] for Residents and Employees at time of [influenza] Outbreak." P. Ex. 2, at 5. That policy goes on to describe two distinct "regimens" for which those medications are used: (1) a "treatment" regimen for persons who exhibit signs or symptoms of influenza or have tested positive

for the virus; and (2) a "prophylaxis" regimen for others who may have been exposed to someone with the virus.[6] *Id.* at 5-7. The Antiviral Procedures state that Tamiflu is "preferred for the prophylaxis regimen," and that the regimen should "[b]egin within 48 hours of outbreak to optimize effectiveness." *Id.* at 5. Like the Influenza Outbreak Guideline, the Antiviral Procedures refer staff to "the CDC website for professionals" for additional "[h]elpful and up to date information." *Id.* at 7.

2. CDC and WDHS Guidance

The CDC website cited in Golden's influenza outbreak policies links the reader to various CDC publications, including the 2011 *Interim Guidance for Influenza Outbreak Management in Long-Term Care Facilities* (CDC Guidance), a copy of which CMS proffered as Exhibit 13. According to its Director of Nursing, Golden "use[s] that resource as a general guide where our own policies are not more specific." P. Ex. 11, at 5.

In order to control or prevent the spread of infection, the CDC Guidance recommends that a long-term care facility implement various measures "[w]hen there is a confirmed or suspected influenza outbreak (2 or more ill residents)."[7] CMS Ex. 13, at 3. Those measures include: influenza testing; "daily active surveillance for respiratory illness among ill residents, health care personnel, and visitors"; and the use of "standard and droplet precautions for all residents with suspected or confirmed influenza."[8] *Id.* at 3-5.

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[6] According to the CDC, "[a]ntiviral chemoprophylaxis is meant for patients and residents who are not exhibiting influenza-like illness but who may be exposed or who may have been exposed to an ill person with influenza, to prevent transmission." Centers for Disease Control and Prevention, *Interim Guidance for Influenza Outbreak Management in Long-Term Care Facilities*, available at http://www.cdc.gov/flu/professionals/infectioncontrol/ltc-facility-guidance.htm.

[7] According to the CDC Guidance, "[i]f there is one laboratory-confirmed influenza positive case along with other cases of respiratory infection in a unit of a long-term care facility, an influenza outbreak might be occurring." CMS Ex. 13, at 3.

[8] "Standard precautions" include basic infection prevention measures – such as "[w]earing gloves if hand contact with respiratory secretions or potentially contaminated surfaces is anticipated," performing "hand hygiene before and after touching [a] resident," and "[c]hanging gloves and gowns after each resident encounter" – that should be performed "regardless of the suspected or confirmed presence of an infectious agent." CMS Ex. 13, at 9; *see also* CMS Ex. 43, at 4, 15-17; CMS Ex. 38, ¶ 9; P. Ex. 1, at 4, 8, 15-17. "Droplet precautions," such as isolation and the use of masks, are designed to prevent or minimize the spread of infection that occurs "through close respiratory or mucous membrane contact with respiratory secretions." CMS Ex. 13, at 5-6; *see also* CMS Ex. 43, at 3, 19; CMS Ex. 38, ¶ 9; P. Ex. 1, at 3, 4, 18.

The CDC Guidance further recommends that long-term care residents "who have confirmed or suspected influenza . . . receive *antiviral treatment* [with a recommended antiviral drug, such as Tamiflu (oseltamivir)] immediately." CMS Ex. 13, at 7 (italics added). In addition, as relevant here, the CDC Guidance states that "[a]ll eligible residents in the entire long-term care facility (not just currently impacted wards) should receive *antiviral chemoprophylaxis* as soon as an influenza outbreak is determined." *Id.* (italics added). The CDC Guidance elaborates on that recommendation as follows:

> When at least 2 patients are ill within 72 hours of each other and at least one resident has laboratory-confirmed influenza, the facility should promptly initiate antiviral chemoprophylaxis to all non-ill residents, regardless of whether they received influenza vaccination during the previous fall. Priority should be given to residents living in the same unit or floor as an ill resident. However, since staff and residents may spread influenza to residents on other units, floors, or buildings of the same facility, all non-ill residents are recommended to receive antiviral chemoprophylaxis to control influenza outbreaks.
>
> Antiviral chemoprophylaxis is recommended for all non-ill residents, regardless of their influenza vaccination status, in long-term care facilities that are experiencing outbreaks.
>
> Antiviral chemoprophylaxis is meant for patients and residents who are not exhibiting influenza-like illness but who may be exposed or who may have been exposed to an ill person with influenza, to prevent transmission.
>
> Use of antiviral drugs for chemoprophylaxis of influenza is a key component of influenza outbreak control in institutions that house residents at higher risk of influenza complications. While highly effective, antiviral chemoprophylaxis is not 100% effective in preventing influenza illness.
>
> CDC recommends antiviral chemoprophylaxis for a minimum of 2 weeks, and continuing for at least 7 days after the last known case was identified.

Id. at 7-8; *see also* CMS Ex. 38, ¶ 10.

Finally, the CDC Guidance recommends that a long-term care facility "consider additional measures to reduce transmission among residents and health care personnel," including: "[l]imit[ing] the number of large group activities in the facility and . . . serving all meals in resident rooms if possible when the outbreak is widespread (involving multiple units of the facility)"; and "[r]estrict[ing] personnel movement from areas of the facility having illness to areas not affected by the outbreak." CMS Ex. 13, at 9.

According to its Director of Nursing, Golden "refer[s] to and use[s] many of the recommendations set forth in" an October 16, 2013 memorandum issued by the WDHS. P. Ex. 11, at 2; *see also* CMS Ex. 1, at 40, 51. That memorandum, which we call the "WDHS Guidance," states that it is "intended as guidance to medical administrative staff of long term care facilities" concerning the prevention and control of "acute respiratory illness" (such as pneumonia and influenza). CMS Ex. 11, at 1.

The WDHS Guidance defines an "acute respiratory illness" (ARI) as illness characterized by two or more of the following: fever, cough (new or worsening productive or non-productive); runny nose or nasal congestion; sore throat; and muscle aches "greater than the resident's norm." *Id.* In addition, the WDHS Guidance defines a "respiratory disease outbreak" in a long-term care facility as three or more residents or staff from the "same unit" of the facility "with illness onsets within 72 hours of each other and who have":

- pneumonia, or
- ARI, or
- laboratory-confirmed viral or bacterial infection (including influenza)

Id. at 2. The WDHS Guidance recommends that the facility implement various preventive measures in response to an outbreak of influenza, including the administration of "antiviral prophylaxis." *Id.* at 2-5. Concerning that measure the WDHS Guidance states:

> Influenza antiviral prophylaxis may prevent further spread of infection and illness during outbreaks of influenza in a [long-term care facility].
>
> When cases of influenza have been confirmed, antiviral prophylaxis should be offered to:
>
> - All residents regardless of vaccination status,
> - All unvaccinated employees, and
> - Those employees vaccinated less than two weeks before the cases were identified.
>
> If exposure is limited to a specific wing or residential area, then antiviral prophylaxis use can be limited to residents and unvaccinated staff in those areas.

Id. at 2-3.

3. Golden's response to influenza in the ACU during late January and early February 2015

Golden's ACU is a "24-bed unit that is physically segregated from the rest of the Center for programming reasons[.]" P. Ex. 11, at 8; P. Ex. 12, at 7-8. Each resident on the ACU shares a room with another resident. CMS Ex. 30, ¶ 5. The five ACU residents identified below (Residents 15, 11, 13, 20, and 12) were between 76 and 93 years old, and three of the five were older than 90 years, when the events at issue in this case occurred (January and February 2015).

On January 22, Resident 15 was hospitalized with symptoms that included fever, cough, and congestion; she tested positive for influenza in the hospital. *See* CMS Ex. 8; CMS Ex. 26, at 26, 37, 57-58 (entries for January 22). In response to Resident 15's illness, Golden isolated and provided Tamiflu to her roommate. P. Ex. 11, at 10; P. Ex. 13, at 10-11. Golden also implemented various unit-wide infection control measures, including posting a memorandum urging facility staff who had not yet received a flu vaccination to get vaccinated or consider taking prophylactic Tamiflu "due to the respiratory symptoms and a confirmed case of influenza" on the ACU.[9] P. Ex. 11, at 10-13; P. Ex. 12, at 9-11.

Also on January 22, the Director of Nursing telephoned a Public Health Nurse at the Douglas County Health Department to report the first confirmed influenza case. P. Ex. 11, at 12. The county nurse instructed the Director of Nursing to "monitor the situation and to notify the Health Department and provide a 'line list' when three confirmed cases [of influenza] were noted within 72 hours . . . ." *Id.*

On January 25, a second resident – Resident 11 – tested positive for influenza. CMS Ex. 8; CMS Ex. 23, at 1, 19. The nursing staff noted on that day that Resident 11 was "flushed" and "lethargic" with "nose dripping" and a temperature of 100.1 degrees. CMS Ex. 23, at 19. In response, Resident 11's physician ordered Tamiflu and "droplet isolation" precautions for both Resident 11 and her roommate. CMS Ex. 23, at 15; P. Ex. 11, at 13; P. Ex. 13, at 11.

On January 26, Resident 15 returned from the hospital with an order for Tamiflu. CMS Ex. 26, at 11. A hospital record indicated that she had not had a fever for 24 hours. P. Ex. 11, at 10. Between January 27 and January 29, Resident 15 ate meals in the dining room. CMS Ex. 26, at 11.

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[9] The staff memorandum, dated January 22, 2015, states that "[f]or staff that are working hands-on or in close proximity with residents with suspected or confirmed influenza illness, you are encouraged to discuss taking Tamiflu with your Family Doctor to prevent becoming ill." P. Ex. 8, at 1. Other unit-wide precautions initiated by Golden included: increasing the frequency of cleaning; re-educating staff regarding "droplet isolation precautions"; instructing staff to limit movement of residents off the ACU; placing signs warning of possible flu in the ACU; advising visitors to the ACU to wear masks; suspending "all activities" on the ACU except for certain "sensory activities"; and reporting flu-related information to the WDHS. P. Ex. 11, at 10-13; P. Ex. 12, at 9.

On January 26, Resident 13, who lived in the room next to Resident 15's room, was tested for influenza. CMS Ex. 8; CMS Ex. 25, at 1, 10, 25-26; CMS Ex. 30, ¶ 5; P. Ex. 11, at 13. A January 26 nursing note indicates that she had a non-productive cough, congestion, and a temperature of 100.7 degrees (which fell to 98.6 degrees after the administration of Tylenol). CMS Ex. 25, at 10. An influenza test came back negative, but Golden confined Resident 13 to her room and used "isolation precautions" in caring for her. *Id.* at 10, 25-26; P. Ex. 11, at 13; P. Ex. 13, at 13.

Also on January 26, Golden's Director of Nursing "conferred with the [Douglas] County Public Health Nurse, who advised that the two confirmed cases [of influenza] by that point did not require further interventions or reports." P. Ex. 11, at 13.

On January 27, Resident 20, who shared a room with Resident 13, was tested for influenza after developing a "congested nonproductive cough." CMS Ex. 27, at 1, 10; CMS Ex. 30, ¶ 5; CMS Ex. 36, ¶ 9. The test was negative. CMS Ex. 27, at 10; P. Ex. 11, at 13. Golden nonetheless implemented isolation precautions for Resident 20 "out of an abundance of caution because . . . [of] concern[ ] that other residents had tested positive for influenza." P. Ex. 11, at 14; P. Ex. 12, at 12.

Beginning on January 29, Resident 15, who had returned to the ACU from the hospital on January 26, began to vomit and have coughing fits, exhibited lethargy, and developed pain on breathing. CMS Ex. 26, at 9-11. She was re-hospitalized the next day, January 30, with aspiration pneumonia and influenza. CMS Ex. 26, at 9, 54; P. Ex. 11, at 15; P. Ex. 13, at 12.

Also on January 30 (at approximately 1:30 p.m.), Resident 12, who lived in the room next to Resident 15's room, tested positive for influenza after experiencing lethargy, fever (99.8 degrees), and other symptoms. CMS Ex. 8; CMS Ex. 24, at 1, 4, 6; CMS Ex. 30, ¶ 5; P. Ex. 11, at 15. In response, Golden initiated a plan of care that placed both Resident 12 and her roommate on "droplet isolation precautions," and their physicians prescribed Tamiflu. CMS Ex. 24, at 3-4, 9; P. Ex. 11, at 15; P. Ex. 12, at 12; P. Ex. 13, at 12.

On January 31 (a Saturday), the nursing staff reported that Resident 20, who had been tested for influenza on January 27, "continue[d] to have" fever, decreased breath sounds, wheezing, and lethargy. CMS Ex. 27, at 9; P. Ex. 11, at 15; P. Ex. 13, at 12. She was hospitalized the same day and diagnosed with influenza and pneumonia. CMS Ex. 27, at 3, 9; P. Ex. 11, at 15; P. Ex. 13, at 12. She returned to Golden on February 3 with an order for Tamiflu and "stayed on isolation precautions [in the ACU] until February 11, 2015." P. Ex. 11, at 16; CMS Ex. 27, at 1-2.

On February 2, Golden's Medical Director ordered prophylactic Tamiflu for 17 ACU residents who were not already receiving that drug. CMS Ex. 16; CMS Ex. 20, at 1; CMS Ex. 21, at 6; P. Ex. 11, at 15; P. Ex. 13, at 12-13. Prior to February 2, the only residents who received antiviral prophylaxis were the roommates of residents who had tested positive for influenza. P. Ex. 13, at 10-12 (indicating that the roommates of Residents 15, 11, and 12 had received prophylactic Tamiflu).

Also on February 2, Resident 13, who had been tested for influenza on January 26 and who thereafter continued to experience cough and chest congestion, was diagnosed with pneumonia and underwent two different influenza diagnostic tests. P. Ex. 11, at 16; *see also* CMS Ex. 25, at 6-9, 22-23. One of those tests (the "swab") was negative, but the second test ("viral panel") came back positive on February 4. P. Ex. 11, at 16; *see also* CMS Ex. 25, at 5-6, 19, 20, 22-23, 29; P. Ex. 11, at 16. In response, Resident 13's physician increased her dosage of Tamiflu and continued preexisting droplet isolation precautions. P. Ex. 11, at 16.

After February 4, "isolation precautions were ended for all of the residents who remained on isolation as each passed seven days since first symptoms and 24 hours after symptoms ended. There were no new cases of influenza reported after February 4, 2015, and every resident but one [presumably, Resident 15] who was diagnosed with flu recovered unremarkably." P. Ex. 11, at 16.

According to a Golden "staff float list," on 12 dates between January 22 (the date of the first laboratory-confirmed case of influenza) and February 6, 2015, a Golden employee moved between a non-ACU part of the facility and the ACU. *See* CMS Ex. 17. In addition, "during the influenza outbreak," ACU residents who were not subject to isolation precautions continued to receive "sensory activities involving all five senses per the ACU protocol in small groups each day." P. Ex. 14, at 1-2; *see also* P. Ex. 11, at 11 ("sensory activities" continued after January 22 for "non-isolated residents receiving programming in small groups on the Unit").

C. *Analysis*

1. Effective December 2014, Golden established written policies calling for use of infection control practices, including measures to prevent or control influenza, that reflected CDC guidelines.

The facts we have just narrated show that, as of December 2014, Golden had an infection control program – built on written policies, including two that specifically addressed influenza – which instructed or advised its staff to follow pertinent CDC guidelines. One of Golden's policies calls for "*all* infection prevention and control practices [to] reflect

current Centers for Disease Control (CDC) guidelines." P. Ex. 1, at 5 (italics added). Both of Golden's influenza-specific policies likewise reveal an intention to follow CDC-recommended practices: both refer the reader to a website containing links to CDC infection control guidelines. P. Ex. 2, at 2, 4. In addition, Golden's Director of Nursing and Medical Director admitted in their declarations that Golden follows CDC recommendations as a matter of policy: the Director of Nursing stated that his staff uses CDC's 2011 *Interim Guidance for Influenza Outbreak Management in Long-Term Care Facilities* (CDC Guidance) as a "general guide" when its "own policies are not more specific" (P. Ex. 11, at 5); likewise, the Medical Director stated that Golden's "policies and procedures generally follow . . . recommendations" in the CDC Guidance (P. Ex. 13, at 4). And both employees declared that Golden's infection control practices and procedures were actually "more stringent" than those called for by either the CDC or the WDHS. P. Ex. 11, at 2, 5; P. Ex. 13, at 4.

2. Golden did not follow the antiviral prophylaxis protocol called for by its infection control program or CDC guidelines in responding to an influenza outbreak in its ACU during January 2015.

The CDC Guidance states that antiviral chemoprophylaxis should be provided to all non-ill residents in the facility "as soon as an influenza outbreak is determined." CMS Ex. 13, at 7. Golden's Influenza Outbreak Guideline defines an "outbreak" as "even one" confirmed case of influenza. P. Ex. 2, at 1. Accordingly, in order to comply with its own definition of "outbreak" and with the CDC Guidance's instruction to provide antiviral chemoprophylaxis as soon as an outbreak is determined, Golden needed to provide antiviral chemoprophylaxis to its residents promptly after Resident 15 tested positive for influenza on January 22, 2015 (a test result that Golden became aware of on that date) and certainly no later than "48 hours after outbreak to optimize effectiveness."[10] P. Ex. 2, at 1. Golden did not do so. As its Medical Director admitted, Golden did not offer or provide prophylactic Tamiflu to residents (other than to the roommates of ACU residents who had tested positive for influenza) until 11 days after Resident 15's diagnosis, on February 2, 2015. *See* P. Ex. 13, at 10-13.

[10] In its appeal brief, Golden does not deny that an outbreak occurred in its ACU in early 2015 but does not tell us *when* it thinks that event occurred (within the meaning of its policies) or when an outbreak should have been "determined" by its staff. Golden's Director of Nursing declared that she "*did* initiate [the facility's] policies and procedures for influenza outbreaks" on January 22, 2015, "when [the] first case of influenza was confirmed." P. Ex. 11, at 10 (italics in original). That statement plainly implies that Golden, in fact, identified an outbreak in its ACU as of January 22, 2015, and Golden's nursing records indicate that staff were aware of the positive test result on that date. *See* CMS Ex. 26, at 57 (entry for 1/22/2015 at 21:10).

Even under the CDC's definition of "outbreak," which is different than Golden's, Golden did not timely administer antiviral prophylaxis to its residents. According to the CDC, an influenza outbreak has occurred "[w]hen at least 2 patients are ill within 72 hours of each other and at least one resident has laboratory-confirmed influenza[.]" CMS Ex. 13, at 7; *see also id.* at 3 (stating that an outbreak "might be occurring" when there is "one laboratory-confirmed influenza positive case" along with "other cases of respiratory infection"). Based on that definition, Lona Mody, M.D., an Associate Professor in the University of Michigan Medical School's Department of Internal Medicine (Division of Geriatric and Palliative Medicine) and witness for CMS, testified that an outbreak existed in the ACU as of January 25, 2015 "because [Resident 15] had tested positive for influenza on January 22 and [Resident 11] also tested positive within three days." CMS Ex. 38, ¶ 11. Golden did not rebut that testimony or Dr. Mody's ensuing conclusion that, under the CDC "threshold for antiviral chemoprophylaxis administration," Golden should have given all of its residents Tamiflu on January 25 but instead waited six more days before doing so. *Id.*

The WDHS Guidance defines the term "outbreak" in a third (and more expansive) way, stating that a "respiratory disease outbreak in a [long-term care facility]" has occurred when "three or more residents and/or staff" have pneumonia, "acute respiratory illness," or "laboratory-confirmed viral or bacterial infection (including influenza)." CMS Ex. 11, at 2. The WDHS Guidance also states that antiviral prophylaxis "should be offered" to a facility's residents "when cases of influenza have been confirmed." *Id.* at 2-3.

Although the Director of Nursing claimed that Golden followed "many of" the WDHS Guidance's recommendations, P. Ex. 11, at 2, he did not state that Golden followed WDHS' definition of "outbreak" – the trigger for administration of antiviral prophylaxis – as opposed to its own or CDC's definition of that term. Nor did Golden argue that WDHS's definition of an outbreak should dictate our conclusion about when staff should have provided antiviral prophylaxis. Indeed, after noting the differences in the definitions of "outbreak" in the WDHS and CDC Guidance, the Director of Nursing stated that "our practice is actually more stringent tha[n] either [of those] set[s] of Guidelines," P. Ex. 11, at 2, and that he "had implemented influenza interventions based on the *first* diagnosed case," *id.* at 14. Thus, the Director of Nursing's sworn statements strongly suggest an understanding on his part that Golden was to "determine" an outbreak based on *its* definition of that term (a single confirmed case of influenza).

Furthermore, under the WDHS definition of "outbreak" (three confirmed cases of influenza with "illness onset" within 72 hours), an outbreak existed in Golden's ACU as of January 31, 2015 because residents 15, 12 and 20 had all tested positive for influenza (Resident 15 for the second time) within the previous 72 hours. Yet, Golden waited another 48 hours after those events to offer antiviral prophylaxis to the 17 ACU residents who had not yet received it.

3. <u>Golden violated its infection control policies by allowing staff to move in and out of the ACU during the outbreak</u>.

Golden's Influenza Outbreak Guideline instructed: "Do not move your staff around the building [when influenza is suspected]. Designated staff should stay on their regularly scheduled area and should not go from floor to floor. . . ." P. Ex. 2, at 3.

CMS alleged that Golden violated that instruction by allowing staff to move between the ACU and other sections of its facility during the outbreak. MSJ at 19. To support that allegation, CMS produced a "staff float list" which shows that from January 22 to February 6, 2015, Golden allowed nine different (named) employees to move between the ACU and other departments a total of twelve times. *See* CMS Ex. 17.

Golden does not deny that such movement occurred or that it violated the letter of its Influenza Outbreak Guideline. In his declaration, the Director of Nursing stated that he "limited staff from other units from being assigned [to the ACU]" during the outbreak "to the extent feasible"; that any staff who were not regularly assigned to the ACU but who worked there during the outbreak "were appropriately trained regarding isolation precautions"; and that he was "aware of no breaches of such precautions." P. Ex. 11, at 12. However, as the ALJ aptly noted, Golden's policy flatly *prohibited* staff from being moved from their regularly assigned work areas during the outbreak. ALJ Decision at 8, citing P. Ex. 2, at 4. The policy created no exceptions based on "infeasibility," however that term might be defined. In addition, the policy did not state or imply that Golden could rely on the assumed efficacy of other precautions (such as staff training on isolation precautions) in order to minimize or counteract the infection transmission risk created by staff being allowed to work outside their regularly assigned areas. To the contrary, the policy instructed Golden to implement "all" of 25 infection control measures – which included *both* the prohibition on staff movement *and* the performance of staff training or retraining in proper infection control practices – in response to an influenza outbreak. *See* P. Ex. 1, at 3 (calling on Golden to "[e]ducate all staff on hand washing/hand hygiene and use of proper barriers" and to "re-educate them on standard and droplet precautions"); P. Ex. 3 (Golden policy describing "droplet" and other "transmission-based isolation precautions").

4. <u>Golden did not comply with the instruction in its Influenza Outbreak Guideline to cancel all resident activities.</u>

Golden's Influenza Outbreak Guideline instructed staff to "[c]ancel all activities . . . if several residents have influenza on a particular wing." P. Ex. 2, at 4. WDHS's survey found, and the director of the ACU confirmed, that during the early 2015 influenza outbreak – in which five different residents contracted influenza or experienced symptoms of respiratory illness – Golden continued to provide daily "sensory activities"

to "small groups" of ACU residents who were not subject to isolation precautions. CMS Ex. 1, at 37, 56; P. Ex. 14, at 2. We agree with the ALJ that these circumstances show that Golden did not heed its own protocol to "[c]ancel *all* activities" (ALJ Decision at 9, quoting P. Ex. 2, at 4 (italics added)) in the affected unit. Like the prohibition on staff movement, the activity ban allowed no exceptions.

5. <u>Golden has not raised a genuine dispute of material fact, and its failure to follow its own infection control protocols regarding antiviral prophylaxis, staff movement, and resident activities constitutes noncompliance with 42 C.F.R. § 483.65.</u>

As the discussion in the previous four sections illustrates, undisputed facts show that in responding to an influenza outbreak in its ACU, Golden did not timely or fully implement the following three protocols called for by its infection control program: (1) administration of antiviral prophylaxis promptly after the occurrence of an influenza outbreak; (2) prohibition of staff movement to and from the ACU; and (3) cancellation of residents' group activities. The evident purpose of those protocols is to minimize or control the spread of a virus having the potential to cause serious or life-threatening illness to residents. Golden's failure to implement the protocols (absent evidence that they were unnecessary or violated professional standards of care) constitutes noncompliance with section 483.65, which requires a SNF not only to establish but to "maintain" – that is, carry out – the policies and procedures of its infection control program. *Heritage House of Marshall Health & Rehab. Ctr.* at 12; *cf. The Laurels at Forest Glenn,* DAB No. 2182, at 18 (2008) (holding that a facility's resident care policies may be "evidence of" what a SNF expected its staff to do in order to comply with quality-of-care requirements in section 483.25 as well as evidence of an applicable "professional standard of care").

In opposing the grant of summary judgment to CMS, Golden focuses heavily on the testimony of its Medical Director, Mark Boyce, M.D. regarding the effectiveness of antiviral prophylaxis. Dr. Boyce stated that, on January 22, 2015, when he learned of the first laboratory-confirmed influenza case, he told the Director of Nursing that he was "not inclined to order prophylactic Tamiflu for the affected unit [the ACU], or for the entire unit" because he had made a "professional judgment," based on an independent review of medical literature, "that prophylactic administration of antiviral medications such as Tamiflu generally is not warranted until at least *three* cases of flu are confirmed." P. Ex. 13, at 8, 11. Dr. Boyce expressed the view that there is currently insufficient or inconclusive evidence of Tamiflu's effectiveness in reducing transmission of the influenza virus or in reducing the rate of complications or hospitalizations of persons who contract the virus. *Id.* at 8-9.

These statements do not create a genuine dispute of material fact about Golden's failure to follow its established infection control program. That program, and its constituent written clinical practice policies and procedures, plainly indicate that Golden expected its staff to follow CDC Guidance in responding to an influenza outbreak. *See* P. Ex. 1, at 8 (stating that "[i]t is important that all infection prevention and control practices reflect current . . . CDC . . . guidelines"). The CDC Guidance, as previously stated, states that antiviral chemoprophylaxis should be provided to all non-ill residents in the facility "as soon as an influenza outbreak is determined." CMS Ex. 13, at 7. Since the facility's policies defined an outbreak as even one diagnosed case of influenza, P. Ex. 2, at 1, the CDC guidance required administration of chemoprophylaxis after the first diagnosis of influenza in Resident 15. While acknowledging that Golden's "policies and procedures generally follow" the CDC Guidance, Dr. Boyce admitted that he departed from that guidance (and, by extension, Golden's infection control program), declaring that he delayed ordering antiviral prophylaxis for ACU residents based on his "professional judgment" that "differs somewhat from the CDC . . . recommendations." P. Ex. 13, at 8.

We reject the suggestion that Golden can meet its regulatory obligation to follow its infection control policy, which adopted the CDC instruction to initiate antiviral prophylaxis immediately upon occurrence of an outbreak of influenza, by acceding to a professional judgment on the part of its Medical Director, Dr. Boyce, to not follow that policy. Under the regulations, Dr. Boyce's role as Golden's Medical Director is to implement the facility's resident care policies, not to override them. *See* 42 C.F.R. § 483.75(i). While Dr. Boyce's professional judgment might well be a factor in developing or amending the facility's policy based on evolving standards regarding the treatment of influenza, once that policy is adopted by the facility, including its Medical Director, the facility must follow it unless and until it is changed. Nor do we see in the CDC Guidance any exception based on professional judgment to the instruction to immediately administer antiviral prophylaxis if an influenza outbreak occurs. Having chosen to fashion Golden's influenza control policies to reflect the CDC Guidance, Golden's staff, including Dr. Boyce, were required to implement those policies consistent with that Guidance.

The record suggests that Dr. Boyce was not even aware he was not following Golden's policy when he delayed ordering prophylactic Tamiflu. More specifically, Dr. Boyce stated in his survey interview that it was Golden's policy not to offer prophylactic Tamiflu unless there were three confirmed cases of influenza in the facility within 72 hours. CMS Ex. 1, at 55; *see also* CMS Ex. 28, ¶ 10; CMS Ex. 36, ¶ 11. This assertion about the facility's policy is clearly incorrect since that policy incorporates the CDC guidance which requires provision of prophylactic Tamiflu immediately after an "outbreak," which Golden's policy defines as a single diagnosed case of influenza. Given the Medical Director's role – recognized in the regulations – to implement facility policy, Dr. Boyce's inability to correctly articulate Golden's influenza control policy is itself troublesome.

Golden suggests that Dr. Boyce's decision not to order administration of Tamiflu ACU-wide immediately after staff identified an outbreak of influenza did not amount to a failure to implement Golden's policies but, rather, was a decision to "interpret and apply" those policies in "specific circumstances" that may have justified deviations from the CDC-recommended practices reflected in those policies. *See* RR at 36 (posing the question, "*who* decides how to interpret and apply the Protocol in specific circumstances"); *id.* at 38 (complaining that the ALJ did not decide "who has the authority to exercise professional judgment about how to implement a clinical policy in specific circumstances"). Nothing in the record supports this suggestion. There is no evidence that, in delaying the provision of antiviral prophylaxis, Dr. Boyce was interpreting or adapting Golden's policies to address a unique clinical situation. Dr. Boyce himself characterized his exercise of "professional judgment" as the straightforward application of a general rule or standard, rather than a response to resident- or outbreak-specific factors, asserting that prophylactic administration of Tamiflu "*generally* is not warranted until" there are three confirmed cases of flu in the facility. P. Ex. 13, at 8 (italics added). This "professional judgment," of course, was fundamentally inconsistent with Golden's policy that even one diagnosed case of influenza constitutes an "outbreak" which, as previously discussed, triggers the CDC's provision for prophylactic administration of Tamiflu among other interventions. The Medical Director was or should have been familiar with Golden's influenza policies, and if Dr. Boyce, in his professional judgment, believed there were circumstances where those policies should not be followed, he should have worked with Golden to modify the policies to address those circumstances.

Finally, we note that Golden's actions were not even consistent with Dr. Boyce's asserted "professional judgment" that prophylactic Tamiflu "generally is not warranted until" there are three confirmed cases of flu in the facility. P. Ex. 13, at 8. Golden had three laboratory-confirmed cases (involving Residents 20, 15, and 12) of influenza on January 30 and 31, 2015, yet another 48 hours elapsed before Dr. Boyce finally ordered antiviral prophylaxis for non-ill residents of the ACU who had not previously received Tamiflu. Neither Dr. Boyce nor Golden's nursing supervisors sought to explain or justify that delay or why it would not constitute noncompliance even under Dr. Boyce's own guideline.[11]

We find no merit in Golden's remaining arguments. Golden contends CMS's case is fatally flawed because section 483.65 did not give Golden notice of the clinical "standards" that staff needed to meet. *See* RR at 33-34. That contention is, as the ALJ noted, a red herring. Section 483.65 imposes on the *SNF* the responsibility to identify

[11] According to the Statement of Deficiencies, Dr. Boyce told surveyors that staff should have called him on Saturday, January 31 to inform him of the confirmed case that day instead of waiting until Monday, February 2. CMS Ex. 1, at 58. He did not disavow that statement in his declaration.

and adopt as policy – and then meet – adequate infection control standards. To read the regulation in any other way "would undercut Congressional intent to ensure quality of care in nursing facilities, since professional standards may change over time." *Omni Manor Nursing Home*, DAB No. 1920, at 11 (2004); *cf. John J. Kane Reg'l Ctr. – Glen Hazel*, DAB No. 2068, at 12 (2007) (noting that the requirement under section 483.25 to provide "necessary care and services" implies an obligation to ensure that services meet "professional standards of quality" not specified in that regulation).

Our understanding and application of section 483.65 here comports with other Board decisions which hold that a SNF's resident care policies may, in appropriate circumstances, be used to judge whether the SNF has complied with Part 483 regulations that impose general quality-of-care obligations. For example, in *Spring Meadows Health Care Center*, the Board held that "it was not improper of CMS to rely on" the facility's own neurological assessment policy in order to assess whether the facility's failure to perform (or adequately perform) such an assessment for a particular resident constituted noncompliance with the quality-of-care standard specified in 42 C.F.R. § 483.25. DAB No. 1966, at 16-17, 19-20 (2005). The Board concluded that the facility's failure to provide care in accordance with the [neurological assessment] policy violated section 483.25 "even though section 483.25 [did] not specifically require that [the facility] have such a policy." *Id.* at 17; *see also The Laurels at Forest Glen,* DAB No. 2182, at 18 (2008) (stating that CMS "may reasonably rely on a facility's policy relating to the care and treatment of its residents as evidencing the facility's understanding of what must be done to attain or maintain residents' highest practicable physical, mental, and psychological well-being, as required by section 483.25"); *Hanover Hill Health Care Ctr.*, DAB No. 2507, at 6 (2013) (observing that "the Board has long held that a facility's own policy may be sufficient evidence both of professional standards of quality and of what the facility has determined is needed to meet the quality of care requirements in section 483.25"). And in *Perry County Nursing Center*, the Board rejected the argument that there was no "independent legal . . . source" for the professional quality standard applied by the administrative law judge to assess the SNF's compliance with 42 C.F.R. § 483.20(k)(3)(i), which states that a SNF's services must "[m]eet professional standards of quality." DAB No. 2555, at 9 (2014). The Board found that the "standards in question [were] found in [the facility's] resident care policies," which, the Board said, may be presumed to reflect "professional standards of quality" absent contrary evidence. *Id.*

With respect to its failure to follow its protocols regarding staff movement and resident activities, Golden asserts that these protocols are mere "examples to guide the Director of Nursing during a flu outbreak" and that its Director of Nursing (and other supervisory staff) should be free to "interpret and apply" the protocols in a way that "balances residents' safety with their clinical needs." *See* RR at 35-36. However, Golden does not point to specific policy language to support its characterization. Golden's Influenza Outbreak Guideline states that the prohibitions on staff movement and resident activities during outbreaks are among 25 precautions that "should be done" when an outbreak is

suspected. P. Ex. 2, at 3. An official instruction to staff that something "should be done" cannot plausibly be interpreted as a mere suggestion in the absence of other qualifying language. No such language can be found in the relevant policy, and no Golden employee came forward to say that the facility's infection control protocols can or should be understood as allowing staff to determine, on an ad hoc basis, the necessity of certain precautions once an outbreak has been identified. *Compare Virginia Highlands Health Rehab. Ctr.*, DAB No. 2339, at 7 (2014) (holding that a facility's hydration policy, while perhaps articulating a standard of care, could reasonably be read to permit the exercise of "nursing judgment" because it called upon an interdisciplinary team to determine if the relevant intervention was "needed"). Even if clinical circumstances might justify a departure from the policy's stated procedures, Golden did not proffer evidence of such circumstances. Golden suggested in its request for review, that staff could reasonably balance the protocol prohibiting group activities during an outbreak against residents' need for "consistent therapeutic [group] programming." *See* RR at 24. But none of Golden's staff testified that residents' "clinical needs" for group activities outweighed the substantial health risks to residents from less-than-full compliance with its influenza control procedures or that the continuation of small group activities during the outbreak was the result of reasoned decision-making about risks and benefits.

Golden contends that the infection control measures it took during the outbreak (apart from the three at issue in this case), particularly in response to the first confirmed case of influenza on January 22, should be considered in deciding whether CMS is entitled to summary judgment. *See* RR at 24-25. The fact that Golden took other precautions is immaterial, as the ALJ held. Golden's infection control policies called on staff to take *multiple* precautions *simultaneously* in order to contain the influenza outbreak. *See, e.g.*, P. Ex. 2, at 3-4 (stating that staff should implement "all" 25 listed measures in response to an influenza outbreak). Those policies do not classify the precautions by relative importance or necessity, nor do they indicate that staff may pick-and-choose, prioritize, or limit which ones to implement in response to an outbreak. And Golden proffered no evidence that the three lapses identified by CMS did not pose substantial risks of harm to residents.

Finally, we note that even if we had reached a conclusion favorable to Golden concerning the prophylaxis issue – to which Golden devotes most of its arguments in this appeal – we would uphold CMS's determination of noncompliance based on the other two protocol failures, about which there is essentially no dispute.

To summarize, CMS proffered evidence that during an influenza outbreak in January 2015, Golden failed to implement three influenza control precautions called for by its infection control program, in violation of its obligation under section 483.65 to carry out that program. In response, Golden has not pointed to, or presented evidence of, any genuine factual disputes – disputes whose resolution could cause a rational trier of fact to

conclude that it was substantial compliance with section 483.65 during the influenza outbreak. Accordingly, we grant summary judgment to CMS on this issue and sustain CMS's determination that Golden was not in substantial compliance with section 483.65 as of January 26, 2015.

6. Golden did not show that CMS's immediate jeopardy determination was clearly erroneous and does not dispute CMS's determination about the duration of the immediate jeopardy.

Immediate jeopardy is "a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301. In order to overturn CMS's determination about the "level" (scope and severity) of a SNF's noncompliance, when it is subject to challenge at all (such as when it affects the applicable range of CMP amounts), a SNF must show that the determination "is clearly erroneous." *Id.* § 498.60(c)(2*); Crawford Healthcare & Rehab.*, DAB No. 2738, at 14-15 (2016). The Board has said that "[t]he 'clearly erroneous' standard means that CMS's immediate jeopardy determination is presumed to be correct, and the burden [on the SNF] of proving the determination clearly erroneous is a heavy one." *Glenoaks Nursing Ctr.*, DAB No. 2522, at 16 (2013).

In its reply brief, Golden suggests that CMS had no factual basis to conclude that the noncompliance had caused or "enhanced [the] risk" of serious harm to residents. Pet.'s Reply Br. at 17-18. The record belies that assertion, however. The noncompliance involved a failure to implement infection control protocols specifically designed and intended to contain an outbreak of a contagious virus which Golden's own influenza control policy says "can and does cause substantial illness and even death among many LTC [long-term care] residents." P. Ex. 2, at 1. Events in the ACU in early 2015 showed that the likelihood of serious harm to residents from the spread of influenza was neither hypothetical nor insubstantial. Five ACU residents contracted influenza within a two-week period, three of whom tested positive for the virus five or more days *after* January 22, the date that Golden says it initiated some of its influenza outbreak protocols. Given that circumstance and Golden's own description of the nature of the health risk to its residents, it clearly was not erroneous for CMS to determine that Golden's failure to fully or promptly implement three influenza control precautions was likely to cause serious harm to residents.

Golden suggests that the rate of infection (what Golden terms the "attack rate") in the facility after the first confirmed cases shows that the precautions it did implement were effective and prevented other infections from occurring or mitigated the risk of harm posed by its three protocol failures. Golden did not point to evidence (or even offer a minimally developed factual argument) supporting the claim that any measures it did take substantially mitigated the likelihood of harm; indeed, Golden's discussion of the

immediate-jeopardy issue is devoid of citations to the record. More important, even assuming staff took some measures that prevented or reduced the risk of additional infections, that does not alter the undisputed facts, discussed above, regarding the multiple confirmed cases of influenza that did exist and Golden's failure to implement or timely implement three of its protocols. CMS's determinations of noncompliance and immediate jeopardy and the ALJ's (and our) affirmance of those determinations are based on those undisputed failures. Moreover, Golden did not rebut the testimony of Dr. Mody (CMS's witness) that "failure to institute infection control measures during an outbreak of Influenza A *increased* the risk that a resident would develop influenza, which can result in serious harm or even death for an elderly person." CMS Ex. 38, ¶ 13 (italics added). In short, Golden made no meaningful attempt to carry its heavy burden to show clear error by CMS, and we affirm the ALJ's immediate jeopardy determination.

Golden does not challenge the ALJ's upholding of CMS's determination regarding the duration of the immediate jeopardy period, that is, that residents were in immediate jeopardy from January 26, 2015 through February 9, 2015. *See* CMS Ex. 1, at 35. Golden had the burden to show clear error in that determination, *Crawford Healthcare & Rehab.* at 18, but did not respond to CMS's presentation on that issue – either in its response to the motion for summary judgment or in the request for review. We therefore sustain CMS's finding that Golden's immediate-jeopardy-level noncompliance with section 483.65 began on January 26, 2015 and lasted through February 9, 2015. *Id.* (summarily affirming an uncontested finding about the duration of a SNF's immediate-jeopardy-level noncompliance).

7. <u>The CMP imposed for the period of immediate jeopardy is not unreasonable.</u>

CMS may impose a per-day CMP for "the number of days a [SNF] is not in substantial compliance with one or more participation requirements . . . ." 42 C.F.R. § 488.430(a). When it imposes that remedy for noncompliance at the immediate-jeopardy level, CMS sets the daily penalty amount within the "upper range" of $3,050 to $10,000. *Id.* §§ 488.408(d)(3)(ii), 488.438(a)(1)(i). A SNF may challenge the reasonableness of the amount of any CMP imposed. *Lutheran Home at Trinity Oaks*, DAB No. 2111, at 21 (2007).

In reviewing the reasonableness of the CMP amount, the Board may not reduce the daily CMP amount below the applicable range. *Crawford Healthcare & Rehab.* at 18-19. In addition, the administrative law judge or the Board may consider only the factors specified in 42 C.F.R. § 488.438(f). *See* 42 C.F.R. § 488.438(e)(3); *Crawford Healthcare & Rehab.* at 19. There is also a presumption that "CMS considered the regulatory factors in choosing a CMP amount and that those factors support the penalty imposed." *Crawford Healthcare & Rehab.* at 19 (citing decisions). "Accordingly, the burden is not

on CMS to present evidence bearing on each regulatory factor, but on the SNF to demonstrate, through argument and the submission of evidence addressing the regulatory factors, that a reduction is necessary to make the CMP amount reasonable." *Id.* (internal quotation marks omitted); *see also Brian Ctr. Health & Rehab. – Goldsboro*, DAB No. 2336, at 12 (2010) ("[T]he burden is on the [facility] to demonstrate, through argument and the submission of evidence addressing the regulatory factors, that a reduction is necessary to make the CMP amount reasonable.").

Here, CMS imposed a $5,100 per day CMP for the period of immediate jeopardy (January 26 through February 9, 2015). In its motion for summary judgment, CMS argued that there is no genuine dispute of material fact concerning the reasonableness of the daily CMP amount and that it is entitled to summary judgment on that issue. MSJ at 22-24. Golden did not respond to that argument. *See* Pet.'s Reply to MSJ, C-15-2887 (Dec. 8, 2015). The ALJ then upheld the $5,100 CMP as "unchallenged" but also concluded, based on a consideration of the relevant regulatory factors, that the CMP "was entirely reasonable." ALJ Decision at 10.

Golden does not object to the ALJ's handling of this issue. We therefore summarily sustain his conclusion that the CMP was reasonable.

Conclusion

We uphold the ALJ's determination that Golden was not in substantial compliance with 42 C.F.R. § 483.65 at the immediate-jeopardy level from January 26 through February 9, 2015. We also uphold the ALJ's conclusion that CMS's CMP for that noncompliance is reasonable.

/s/
Constance B. Tobias

/s/
Susan S. Yim

/s/
Sheila Ann Hegy
Presiding Board Member