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APPENDIX

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Appendix 1a

PUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 25-1669

SLIGO CREEK CENTER,

Petitioner,

v.

UNITED STATES DEPARTMENT OF HEALTH &
HUMAN SERVICES; ROBERT F. KENNEDY, JR.,
Secretary of the United States Department of Health
and Human Services,

Respondents.

AMERICAN HEALTH CARE ASSOCIATION;
THE NATIONAL CENTER FOR ASSISTED
LIVING,

Amici Supporting Petitioner.

On Petition for Review of an Order of the
Department of Health & Human Services. (A-21-12)

Argued: May 5, 2026

Decided: June 5, 2026

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Before RUSHING and HEYTENS, Circuit Judges,
and FLOYD, Senior Circuit Judge.

Petition denied by published opinion. Judge Heytens wrote the opinion, which Judge Rushing and Judge Floyd joined.

ARGUED: Joseph L. Bianculli, HEALTH CARE LAWYERS, PLC, Deale, Maryland, for Petitioner. David L. Peters, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Respondents. Mark Emerson Reagan, HOOPER, LUNDY & BOOKMAN, P.C., San Francisco, California, for Amici Curiae. **ON BRIEF:** Brett A. Shumate, Assistant Attorney General, Michael S. Raab, Daniel Aguilar, Civil Division, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Respondents. David J. Vernon, Rachel L. Zacharias, Sheryl B. Xavier, HOOPER, LUNDY & BOOKMAN, P.C., Washington, D.C., for Amici Curiae.

TOBY HEYTENS, Circuit Judge:

Nursing homes “must comply with numerous statutory and regulatory requirements” to participate in—*i.e.*, receive reimbursement from—Medicare. *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 6 (2000). When participating facilities fail to comply with those requirements, Congress has authorized the Secretary of Health and Human Services (HHS) to impose various consequences, including civil

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monetary penalties. See 42 U.S.C. § 1395i-3(h)(2)(B). Our primary question here: When the Secretary commences administrative proceedings against a Medicare participant seeking monetary penalties, does the Seventh Amendment guarantee that participant the right to a jury trial? We hold the answer is no. And because we see no other basis to disturb the challenged decision here, we deny the petition for review.

I.

Petitioner Sligo Creek Center ran a Medicare-participating nursing home in Montgomery County, Maryland. In 2015, county health officials informed petitioner that two facility employees and a former resident had been diagnosed with active tuberculosis (TB). The county officials met with petitioner's staff "to discuss [a] TB contact investigation and [a] response to the situation." JA 69. The officials claim they told petitioner's staff that the facility "was at high risk for TB transmission" and that—although the county would provide guidance and oversight—"[p]etitioner's staff w[ere] responsible for testing its residents for TB and for follow up treatment." *Id.*

Petitioner's internal policies included a protocol for TB testing and treatment consistent with standard recommended practices. The protocol stated that, once an active case was confirmed, all residents should receive skin tests for TB and those who tested positive should then get a chest x-ray. A positive skin test and positive x-ray indicate active TB, while a positive skin test and negative chest x-ray indicate a latent TB infection. Although latent TB is asymptomatic and noncontagious, untreated latent TB can convert to active TB, which can be dangerous and even deadly. Petitioner's protocol required it to "proceed

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with evaluati[ng]” residents with positive skin tests and negative chest x-rays for latent TB treatment. JA 176-77. That requirement was consistent with federal, state, and county guidance recommending that nursing home residents with latent TB receive treatment “unless” it is “contraindicated or refused.” JA 69 (first quote); JA 86 (second quote).

Petitioner followed the first few steps of this protocol. It administered skin tests, and more than two dozen residents tested positive. Petitioner then gave those residents chest x-rays. All chest x-rays were negative, indicating latent TB infections.

Under the protocol, petitioner was next supposed to “proceed with evaluat[ing]” those residents for latent TB treatment. JA 176; accord Petr. Reply Br. 12. But HHS later concluded—and petitioner now admits—that petitioner neither ordered nor administered latent TB treatment for residents with positive skin tests and negative x-rays.¹ Nor did petitioner explain in any of those residents’ records *why* the facility was not administering latent TB treatment. Indeed, petitioner “conceded” to HHS that it never even “noted” any formal latent TB diagnosis “in any of the resident[s]’ clinical records because no physician from the county or the facility rendered such a diagnosis.” JA 97.

More than a year after the residents’ negative chest x-rays, a state health agency received “a substantial allegation” about petitioner’s “noncompliance” with

¹ One such resident received latent TB treatment because an unaffiliated physician independently evaluated that resident for a kidney transplant and prescribed the treatment.

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Medicare’s participation requirements. JA 72 (quotation marks removed). After an investigation, the state agency determined petitioner “failed to ensure timely follow up of the treatment and management of multiple residents who were identified at risk for exposure to a serious infectious disease” (that is, active TB) “and failed to record in [those] residents’ clinical records the rationale for treatment/non treatment for” latent TB. *Id.* (alterations and quotation marks removed). The state agency thus concluded petitioner violated 42 C.F.R. § 483.65 (2016), which required each Medicare-participating nursing home to:

establish and maintain an infection control program . . . under which it—(1) Investigates, controls, and prevents infections in the facility; (2) Decides what procedures, such as isolation, should be applied to an individual resident; and (3) Maintains a record of incidents and corrective actions related to infections.

§ 483.65(a) (2016).² The state agency also concluded petitioner’s noncompliance created “immediate jeopardy,” JA 72, which federal regulations define as “a situation in which [a] 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. The HHS component that administers Medicare “concurred with” the state agency’s conclusions, determined when

² Although the regulation has since been revised, the parties agree the version quoted above was in effect during all relevant times.

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the “immediate jeopardy” began and ended, and “imposed a . . . per-day [civil monetary penalty]” on petitioner for that period. JA 73.

Petitioner requested and received a hearing in front of an administrative law judge (ALJ) to contest both “the finding of ‘immediate jeopardy’ noncompliance” with the relevant regulation “and the associated” fine. JA 73. The parties introduced “voluminous” evidence, including expert testimony. *Id.* The ALJ rejected petitioner’s arguments, concluding: (1) petitioner had been noncompliant; (2) the noncompliance caused immediate jeopardy during the period HHS asserted; and (3) the fine was reasonable. Petitioner timely sought review from the HHS Departmental Appeals Board, which affirmed the ALJ’s decision.

We have jurisdiction to review the Appeals Board’s decision under 42 U.S.C. § 1395i-3(h)(2)(B)(ii), which incorporates the judicial review provisions contained in Section 1320a-7a(e). We determine *de novo* whether agency action complies with the Constitution. See, *e.g.*, *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 392 (2024). In contrast, the agency’s “findings . . . with respect to questions of fact” are “conclusive” so long as they are “supported by substantial evidence on the record considered as a whole.” 42 U.S.C. § 1320a-7a(e).

II.

Petitioner chiefly argues that HHS’s jury-less adjudication of this proceeding for monetary fines violated the Seventh Amendment as construed in *SEC v. Jarkesy*, 603 U.S. 109 (2024). Like the Third Circuit in an analogous case, we are “unpersuaded” that

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Jarkesy entitles petitioner to a jury trial in this context. *Axalta Coating Sys. LLC v. Federal Aviation Admin.*, 144 F.4th 467, 473 (3rd Cir. 2025).

The Seventh Amendment declares that “the right of trial by jury shall be preserved” “[i]n Suits at common law.” U.S. Const. amend. VII. Under *Jarkesy*, we “conduct[] a two-part analysis” to determine whether petitioner was entitled to a jury trial here. *Axalta*, 144 F.4th at 473. *First*, we ask, as a “threshold issue,” “whether this action implicates the Seventh Amendment” at all. *Jarkesy*, 603 U.S. at 120. *Second*—and only if the answer to that first question is yes—we ask “whether the ‘public rights’ exception to Article III jurisdiction applies.” *Id.*; accord *Axalta*, 144 F.4th at 473, 475; see also *AT&T, Inc. v. Federal Comm’n’s Comm’n*, 149 F.4th 491, 497-502 (5th Cir. 2025) (conducting this two-step analysis), cert. granted, 2026 WL 73092 (U.S. Jan. 9, 2026) (mem.) (No. 25-406).³

We make quick work of the first step. The government “does not contest that the money penalty challenged here ‘implicates the Seventh Amendment.’” Gov’t Br. 26 (quoting *Jarkesy*, 603 U.S. at 125); accord Oral Arg. 24:33-25:06. We thus decide this case on the

³ During oral argument, petitioner suggested—echoing an amicus brief—that there may not even be a “‘public rights’ exception to Article III jurisdiction.” *Jarkesy*, 603 U.S. at 120; see Oral Arg. 9:42-:55. That argument fails twice. *First*, petitioner failed to preserve any such argument by not making it in the opening brief. See *Grayson O Co. v. Agadir Int’l LLC*, 856 F.3d 307, 316 (4th Cir. 2017). *Second*, the current “law on the books” recognizes a public rights exception and we as an inferior court have no authority to abrogate it. *Axalta*, 144 F.4th at 484 (Bibas, J., concurring); cf. *Jarkesy*, 603 U.S. at 127 (concluding that case “does not fall within the exception”).

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assumption that *Jarkesy*'s first requirement is satisfied.

That leaves the second step: “whether the public rights doctrine justifies the administrative adjudication of [HHS]’s enforcement action.” *Axalta*, 144 F.4th at 475. To be sure, *Jarkesy* described some of the Court’s public rights “precedents” as “confusing,” 603 U.S. at 130 (quotation marks removed). But we agree with the Third Circuit that the *Jarkesy* Court “resolved the public rights question . . . in a notably uncomplicated way: by analogizing [*Jarkesy*’s] enforcement action to the action at issue in one public rights precedent—*Granfinanciera*, *S.A. v. Nordberg*, 492 U.S. 33 (1989)—and distinguishing it from the enforcement action at issue in another—*Atlas Roofing Co. v. Occupational Safety & Health Review Commission*, 430 U.S. 442 (1977).” *Axalta*, 144 F.4th at 473-74. Taking the same approach, we ask whether the enforcement proceeding here “more closely resembles the essentially common law action in *Granfinanciera*” or “the action in *Atlas Roofing*.” *Id.* at 475; see *id.* (noting *Jarkesy* “distinguished, but did not overrule, . . . *Atlas Roofing*”).

Jarkesy explained the difference between *Granfinanciera* and *Atlas Roofing* and why the issue before it fell on *Granfinanciera*’s side of the line. In *Jarkesy*—as in *Granfinanciera*—Congress had “simply reclassified a pre-existing, common law cause of action.” *Granfinanciera*, 492 U.S. at 60. The actions in both *Jarkesy* and *Granfinanciera*, though not identical to any common law causes of action, “target[ed] the same basic conduct as” well-recognized common law actions, “employ[ed] the same terms of

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art, and operate[d] pursuant to similar legal principles.” *Jarkesy*, 603 U.S. at 134. In contrast, the statute authorizing the enforcement action in *Atlas Roofing* “did not borrow its cause of action from the common law,” avoided “common law terms of art,” and created a “self-consciously novel” type of action “unknown to the common law.” *Id.* at 136-37 (quoting *Atlas Roofing*, 430 U.S. at 461).

Like the Third Circuit in *Axalta*, we conclude petitioner had no Seventh Amendment right to a jury trial here because this action “cannot be distinguished from the enforcement action considered in *Atlas Roofing*.” *Axalta*, 144 F.4th at 475-76. As in *Atlas Roofing*, Congress did not merely repackage (or assign to a different party) a common law cause of action when it authorized proceedings like the one HHS initiated here. See *Jarkesy*, 603 U.S. at 135; cf. *Sun Valley Orchards, LLC v. U.S. Dep’t of Lab.*, 148 F.4th 121, 124, 128-29 & n.4 (3rd Cir. 2025) (concluding claims brought under a statute authorizing the Secretary of Labor to sue on migrant laborers’ behalf to “enforce[]” the laborers’ “work contract[s]” sufficiently “resemble[d] [a] common law breach of contract” claim to distinguish the case from *Atlas Roofing*), cert. granted, 2026 WL 1127242 (U.S. Apr. 27, 2026) (mem.) (No. 25-966). Instead, Congress created a detailed series of new requirements that apply only to “skilled nursing facilit[ies]” that voluntarily participate in Medicare, and are administered by both state and federal government actors. 42 U.S.C. § 1395i-3(a) (defining that term); see § 1395i-3(a)-(k) (laying out the requirements); cf. *Jarkesy*, 603 U.S. at 137 (describing the statute authorizing the *Atlas Roofing* action as “self-consciously novel” “[i]n both concept and execution”).

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Those requirements are enforced by an intricate and “novel” enforcement scheme that would have been “unknown to the common law.” *Jarkesy*, 603 U.S. at 138-39 (quotation marks removed); see *id.* at 137 (distinguishing schemes that merely “enable the Federal Government to bring or adjudicate claims that traced their ancestry to the common law”). Indeed, petitioner conceded at oral argument (see Oral Arg. 2:35-4:35), that it would have had no right to a jury trial had regulators refrained from seeking a monetary fine and instead withheld reimbursement, see 42 U.S.C. § 1395i-3(h)(2)(B)(i); “appoint[ed] temporary management to oversee the operation of [petitioner’s] facility,” § 1395i-3(h)(2)(B)(iii); or even terminated its ability to participate in Medicare altogether, see § 1395i-3(h)(2)(A)(i). “*Atlas Roofing* binds us. And under its rule, this case involves public rights.” *Axalta*, 144 F.4th at 482 (Bibas, J., concurring).

Seeking to avoid that conclusion, petitioner insists this enforcement scheme is analogous to unspecified (but nonetheless “traditional”) common law tort “concepts,” “obligation[s],” “standards of care,” and “penalt[ies].” Petr. Reply Br. 4-6 (emphasis removed). We disagree.

The first reason for our disagreement involves the underlying basis for the relevant obligation. True, the HHS enforcement action here involved petitioner’s failure to fulfill a duty. But that duty did not stem from any common law duty of care that applies to all people or those who participate in a particular type of activity. Instead, the duty here arose from petitioner’s choice to participate in a voluntary government program (Medicare) where public funds are spent to achieve public benefits. The statute and regulation

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the agency concluded petitioner violated required it to “establish and *maintain*” an adequate infection control policy, 42 U.S.C. § 1395i-3(d)(3)(A) (emphasis added); accord 42 C.F.R. § 483.65 (2016), which includes “comply[ing] with [petitioner’s] own policies and relevant state and local public health authority requirements.” Amicus Br. 22. We see no indication that those policies and requirements—which can be quite detailed and “technical,” *Almy v. Sebelius*, 679 F.3d 297, 302 (4th Cir. 2012) (quotation marks removed)—simply codify and restate general common law tort duties of care.

What is more, the obligations at issue here are—unlike common law torts—untethered to any injury. “Suits at common law to vindicate private rights required both *injuria* (a legal wrong) and *damnum* (actual, concrete harm).” *In re: Express Scripts, Inc.*, __ F.4th __, __ n.8 (4th Cir. 2026) [2026 WL 13555370, at *5, n.8]. Here, in contrast, Congress has authorized HHS to take various actions—including imposing monetary penalties—even when no resident has suffered or is at immediate risk of suffering harm. See 42 U.S.C. § 1395i-3(h)(2)(A)(i) (authorizing “any of the remedies described in subparagraph (B)” even absent immediate jeopardy). And even when (as here) HHS seeks greater penalties because a facility “immediately jeopardize[d] the health or safety of its residents,” § 1395i-3(h)(2)(A)(ii), HHS *still* is not required to show that any resident suffered actual harm. See 42 C.F.R. § 488.301 (defining “[i]mmediate jeopardy” as “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” (emphasis added));

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see also § 488.845(b) (describing factors affecting the size of a penalty).

Thus, having considered the nature of the enforcement proceeding here, we conclude it is not sufficiently analogous to any common law tort to be properly characterized as just a “reclassified” common law tort action. *Axalta*, 144 F.4th at 474 (quotation marks removed).

Petitioner and its amici also briefly suggest the enforcement proceeding here can be analogized to a common law contract action. Once again, we disagree. To be sure, facilities must “execute a [p]rovider [a]greement” with the government “to participate in” Medicare. Amicus Br. 15 n.5. But as we just explained, Congress authorized enforcement actions like this one for mere violations of statutory and regulatory obligations without requiring the government to incur any actual damages as a non-breaching party to a provider agreement. See 42 U.S.C. § 1395i-3(h). We know of no similar common law contract claims.

Like *Atlas Roofing*, this case involves “a new cause of action, and remedies therefor, unknown to the common law.” 430 U.S. at 461. This case is also “markedly different from the fraud cause of action considered in *Granfinanciera* and *Jarkesy*.” *Axalta*, 144 F.4th at 477. So, like the Third Circuit in *Axalta*, we conclude that HHS’s ability “to enforce” the statutory and regulatory obligations at issue here “is a public right that Congress may assign to the executive branch for adjudication without offense to the Seventh Amendment.” *Id.*⁴

⁴ Given our holding that petitioner had no right to a jury trial, we need not reach petitioner’s “corollary” contention that HHS

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III.

Petitioner’s remaining challenges—that HHS acted arbitrarily or capriciously and that the record does not support the agency’s decision—also fail. HHS concluded that: (1) the then-applicable version of 42 C.F.R. § 483.65 required petitioner to follow its internal infection control policy; and (2) petitioner violated the policy by failing to “proceed with evaluati[ng]” its residents with positive skin tests and negative x-rays for latent TB treatment. JA 79-80. Both conclusions survive judicial scrutiny.

Start with petitioner’s assertion that HHS’s decision was arbitrary or capricious because it penalized petitioner’s failure to meet “new[,] *implied* regulatory requirements.” Petr. Br. 45; see 5 U.S.C. § 706(2)(A). Petitioner insists that, under the relevant statute and regulations, the only thing it had to do was follow county health officials’ orders, and because the county issued no orders, it fulfilled those obligations by doing nothing. We disagree. The statute and regulations required petitioner not just to “establish” “an infection control program” but also to “maintain” that program. 42 U.S.C. § 1395i-3(d)(3)(A); 42 C.F.R. § 483.65 (2016). Petitioner does not dispute HHS’s conclusion that its program *required* petitioner to “evaluat[e]” residents with positive skin tests and negative x-rays “for” latent TB treatment. JA 176; see Petr. Reply Br. 12. Because petitioner thus had notice of its obligation to conduct those evaluations, HHS did not impose any impermissible “ad hoc” requirements. Petr. Br. 46 (quotation marks removed); cf. *Golden Living Ctr.-*

“should have held off seizing—or should have returned”—certain funds pending any such trial. Petr. Br. 44.

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Mountain View v. Secretary of Health & Hum. Servs., 832 Fed. Appx. 967, 974-83 (6th Cir. 2020) (holding it was arbitrary and capricious to penalize a facility for “fail[ing] to consider adding additional staffing” because no statute or regulation—either expressly or through incorporation—required facilities to do so).⁵

The record also contains “evidence that a reasonable mind might accept as adequate to support [HHS’s] conclusion” that petitioner did not, in fact, proceed with the required evaluations. *Putnam Ctr. v. United States Dep’t of Health & Hum. Servs.*, 770 Fed. Appx. 630, 638 (4th Cir. 2019) (quotation marks removed) (explaining 42 U.S.C. § 1320a-7a(e)’s “substantial evidence” standard). As the ALJ found (and petitioner did not contest), residents with positive skin tests and negative x-rays had “clinical records” that lacked *any* “note[s]” of their latent TB diagnoses. JA 97. Petitioner also “provided no evidence that [its] attending physicians or nurse practitioners were asked to evaluate th[ose] residents” “for [latent TB] treatment or asked to order [such] treatment; and if not, why not.” JA 98. But see 42 C.F.R. § 483.65(a)(1) (requiring facilities to “maintain an infection control program” “under which” they “[m]aintain[] a record of . . . corrective

⁵ In its reply brief, petitioner also argues its policy’s direction to “proceed with evaluation” for latent TB treatment for residents with positive skin tests and negative x-rays did not require petitioner to “do the[] evaluations.” Petr. Reply Br. 11 (emphasis added). For one thing, petitioner forfeited that argument by failing to raise it in its opening brief. See *Grayson O*, 856 F.3d at 316. For another, we disagree. The policy is internal and thus governs only petitioner, directing it (and only it) to proceed with—in other words, conduct—such evaluations.

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actions related to infections”). We thus reject petitioner’s assertion that the agency’s decision was not supported by substantial evidence.

* * *

The Seventh Amendment did not guarantee petitioner the right to a jury trial here, and HHS’s decision was supported by substantial evidence and neither arbitrary nor capricious. The petition for review is

DENIED.

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FILED: June 5, 2026

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 25-1669
(A-21-12)

SLIGO CREEK CENTER
Petitioner

v.

UNITED STATES DEPARTMENT OF HEALTH &
HUMAN SERVICES; ROBERT F. KENNEDY, JR.,
Secretary of the United States Department of Health
and Human Services

Respondents

AMERICAN HEALTH CARE ASSOCIATION;
THE NATIONAL CENTER FOR ASSISTED
LIVING

Amici Supporting Petitioner

JUDGMENT

In accordance with the decision of this court, the petition for review is denied.

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This judgment shall take effect upon issuance of this court's mandate in accordance with Fed. R. App. P. 41.

/s/ NWAMAKA ANOWI, CLERK

Appendix 18a

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

Sligo Creek Center
Docket No. A-21-12
Decision No. 3191
May 23, 2025

**FINAL DECISION ON REVIEW OF
ADMINISTRATIVE LAW JUDGE DECISION**

Sligo Creek Center (Petitioner), a Maryland skilled nursing facility (SNF), requests review of the October 23, 2020 Administrative Law Judge (ALJ) decision, *Sligo Creek Center*, DAB CR5745 (2020) (ALJ Decision). The issue before the ALJ was whether Petitioner was in substantial compliance with the requirement to adopt and implement infection control policies in 42 C.F.R. § 483.65, from June 14, 2016 through December 11, 2016. The ALJ concluded that: (i) Petitioner was not in substantial compliance with section 483.65 as alleged by the Centers for Medicare and Medicaid Services (CMS); (ii) CMS's determination that Petitioner's noncompliance with section 483.65 posed immediate jeopardy to resident health and safety from June 14 through October 5, 2016 was not clearly erroneous; and (iii) the \$12,541 per-day civil money penalty (CMP) that CMS imposed against Pe-

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itioner for the period of immediate jeopardy was reasonable.¹ For the reasons discussed below, we affirm the ALJ Decision.

Legal Background

A. Social Security Act and Medicare Regulations

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(b), 488.400. Substantial compliance requires a level of compliance “such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm.” *Id.* § 488.301. The term “noncompliance,” as used in the applicable regulations, is synonymous with lack of substantial compliance. *Id.* The participation requirements at issue in this appeal include the requirement to establish and maintain an infection control program found at 42 C.F.R. § 483.65,² which required:

¹ CMS also alleged violations of 42 C.F.R. §§ 483.20(k)(3)(i), 483.35(i), and 483.70(h)(4), but Petitioner did not challenge them, or the remedy imposed.

² In October 2016, the participation requirements for long-term care facilities in subpart B of Part 483, including the requirements related to infection control, were revised, effective November 28, 2016. Final Rule, Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities, 81 Fed. Reg. 68,688 (Oct. 4, 2016); 82 Fed. Reg. 32,256 (July 13, 2017) (technical corrections). The revision of the infection control requirements was significant, but the ALJ determined that the revision incorporated the pre-revision sections 483.65(a) and (b) into section 483.80(a). See ALJ Decision at 1-2 n.1; 42 C.F.R. § 483.80. The ALJ notified the parties of the plan to use the version in effect in October 2016 and the parties did not object.

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The facility 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.

(a) Infection control program. The facility must establish an infection control program under which it—

- (1) Investigates, controls, and prevents infections in the facility;
- (2) Decides what procedures, such as isolation, should be applied to an individual resident; and
- (3) Maintains a record of incidents and corrective actions related to infections.

(b) Preventing spread of infection.

- (1) When the infection control program determines that a resident needs isolation to prevent the spread of infection, the facility must isolate the resident.
- (2) The facility must prohibit employees with a communicable disease or

See ALJ Decision at 1- 2 n.1; *see also* Transcript (Tr.) at 99-100. Like the ALJ, we apply the regulations in effect in October 2016 when the state survey agency conducted the complaint investigation and survey in this case. *See Consulate Healthcare of Jacksonville*, DAB No. 3119, at 1 n.1 (2023) (citing *North Las Vegas Care Ctr.*, DAB No. 2946, at 1.n.1 (2019)).

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infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease.

(3) The facility must require staff to wash their hands after each direct resident contact for which handwashing is indicated by accepted professional practice.

Compliance with Medicare participation requirements is verified through onsite surveys performed by state survey 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 (SOD) that organizes deficiency findings by alpha-numeric “Tags” corresponding to regulatory requirements and CMS guidance.³ *See id.* § 488.110(1), (m); *Vibra Hospital of Charleston-TCU*, DAB No. 3094, at 2 n.2 (2023); *see generally* CMS Pub. 100-07, State Operations Manual (SOM), Chapter 7, Survey and Enforcement Process for Skilled Nursing Facilities & Nursing Facilities; *Cross Creek Health Care Ctr.*, DAB No. 1665, at 7 (1998) (explaining that the SOM “is distributed to state survey

³ The version of the SOM in effect at the time of the survey can be found at CMS Ex. 51. Specifically, it calls for all infection prevention and control practices to reflect current CDC guidelines and consistently comply with state and local health department requirements (such as COMAR) for reporting communicable diseases. CMS Ex. 51, at 5, 10. Although the SOM does not have the force and effect of law, the provisions of the Act and regulations interpreted clearly do have such force and effect. *See Ind. Dep’t. of Pub. Welfare v. Sullivan*, 934 F.2d 853 (7th Cir. 1991); *N.W. Tissue Ctr. v. Shalala*, 1 F.3d 522 (7th Cir. 1993).

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agencies to assist them in conducting facility surveys”). A SOD also indicates the survey agency’s assessment of the “seriousness” (addressing the scope and severity) of any cited deficiency. *Id.* §§ 488.404(a)-(b). The most serious noncompliance poses immediate jeopardy, meaning it “has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident.” *Id.* § 488.301 (defining “immediate jeopardy”).

CMS may impose one or more enforcement “remedies” on a SNF found to be out of substantial compliance. Act § 1819(h); 42 C.F.R. §§ 488.400; 488.402(b)-(c); 488.404; 488.406; 488.408(a)-(e). Available remedies include a CMP, assessed either per day or per incident. 42 C.F.R. §§ 488.406(a)(3); 488.430. When CMS assessed the remedy here, daily CMPs could range from \$6,291 to \$20,628 per day for noncompliance posing immediate jeopardy, and from \$103 to \$6,188 per day for less serious noncompliance.⁴ *Id.* §§ 488.408(d)(1)(iii), (e)(1)(iii); 488.438(a)(1)(i)-(ii). Within either range, CMS sets an amount by considering specified factors. *Id.* §§ 488.404; 488.408(b), (d)(2), (e)(2); 488.438(b), (f). A per-day CMP may accrue “as early as the date that the facility was first out of compliance” and continues until it achieves substantial compliance, or its provider agreement terminates. *Id.* §§ 488.440(a)(1), 488.454(a).

A SNF may appeal a determination of noncompliance that led to the imposition of a remedy by requesting an ALJ hearing and appealing any unfavorable

⁴ Under the regulation, the range of CMPs that CMS may impose is adjusted annually for inflation under 45 C.F.R. Part 102. See 42 C.F.R. § 488.438(a) (Oct. 1, 2016); see also Interim Final Rule, Adjustment for Civil Monetary Penalties for Inflation, 81 Fed. Reg. 61,538, 61,563 (Sept. 6, 2016).

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ALJ decision to the Board. 42 C.F.R. §§ 488.408(g)(1), 498.3(b)(13), 498.5(b)-(c). However, certain issues are not appealable, including CMS's choice of remedy and CMS's noncompliance level determination (unless it would affect the applicable CMP range). *Id.* §§ 488.408(g)(2); 498.3(b)(13)-(14); *see also Meridian Nursing Center*, DAB No. 2265, at 13, 16 (2009), *aff'd Fal-Meridian, Inc. v. U.S. Dep't of Health & Human Servs.*, 604 F.3d 445 (7th Cir. 2010) (citing *Ridge Terrace*, DAB No. 1834, at 7 (2002)).

B. U.S. Centers for Disease Control and Prevention (CDC) Guidelines⁵

Tuberculosis (TB) is an infectious disease that is caused by the bacterium *Mycobacterium tuberculosis* (*M. tuberculosis*). *M. tuberculosis* is carried in airborne droplets and is spread by people who have pulmonary or laryngeal TB when they cough, sneeze, shout, or sing. TB is not normally spread by surface contact. However, *M. tuberculosis* can remain airborne on normal air currents in a building for a prolonged period and can spread throughout a room or building. Infection occurs usually within two to 12 weeks when a person inhales the droplet with *M. tuberculosis*, at which point an individual tests positive when tested for TB. *See* CMS Ex. 41, at 6, 115-16; CMS Ex. 42, at 2-3; CMS Ex. 53, at 9.

Latent TB infection (LTBI) is a condition in which a person is infected with *M. tuberculosis* but does not have active TB. People with LTBI are asymptomatic,

⁵ Our decision, like that of the ALJ, only refers to CDC publications in the record. For all exhibits that are full or excerpted portions of the Guidelines, we refer to the exhibit page numbers rather than the original document's page numbers.

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do not feel sick, have a positive skin test but a negative chest x-ray (CXR) for TB, and do not transmit the disease. A person infected with LTBI is at risk for progressing to TB. Treatment (referred to as preventative therapy, chemoprophylaxis, or prophylaxis) is indicated for those at risk for progression to active TB. *See* CMS Ex. 41, at 46; CMS Ex. 53, at 4; *see also* CMS Ex. 49, at 126-29. For most persons, the only evidence of LTBI is an immune response against mycobacterial antigens demonstrated by a positive skin test or a blood antigen assay such as QuantiFERON®-TB Gold test (QFT-G).⁶ CMS Ex. 53, at 12. Once a person has contracted LTBI, the risk for progression to active TB varies. The greatest risk for progression to disease occurs within the first 2 years after infection. *Id.*

TB and infectious TB mean that the disease caused by *M. tuberculosis* is clinically active and patients are generally symptomatic. *See* CMS Ex. 53, at 4. Infectious TB refers to active TB of the lungs or larynx. People with infectious TB have the potential to transmit the disease. *Id.* This decision will use the terms “LTBI” and “active TB.”

⁶ QFT-G is a Food and Drug Administration (FDA)-approved blood assay test that provides more accurate results than skin tests and can be used in all circumstances in which the skin test is used, including contact investigations and evaluation of those who had received the Bacille Calmette-Guérin (BCG) vaccination. CMS Ex. 39, at 18. The BCG vaccine is used in most countries where TB disease is endemic. The vaccine is effective in preventing disseminated and meningeal TB disease in infants and young children. It may have approximately 50% efficacy for preventing pulmonary TB disease in adults. *See* CMS Ex. 41, at 110.

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CDC guidance further provides:

- Residents and staff of congregate settings such as long-term care facilities are among those at highest risk for exposure and infection. CMS Ex. 41, at 7.
- Treatment of LTBI is essential to control and eliminate TB because it substantially reduces the risk that *M. tuberculosis* will progress to active TB. *Id.* at 55.
- Persons at high risk for progression from LTBI to active TB include people infected with *M. tuberculosis* within the previous two years. *Id.* at 7.
- Approximately five percent of people with newly acquired LTBI progress to active TB within two years if there is no intervention. CMS Ex. 53, at 37.
- Approximately five to 10 percent of people with LTBI who are not treated will develop active TB during their lifetime. CMS Ex. 30, at 7; CMS Ex. 41, at 6.
- Health care facilities pose an increased risk for transmission of TB due to the congregate setting. CMS Ex. 30, at 9; CMS Ex. 41, at 7, 29; CMS Ex. 53, at 17.
- Elderly residents in SNFs and nursing facilities (NFs) “are almost twice as likely to acquire TB as those living in the community,” accordingly the CDC recommends that nursing home residents with LTBI “should be offered treatment according to current recommendations.” CMS Ex. 53, at 60.

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- Control of TB in nursing homes requires, among other things, prompt detection and diagnosis, isolation of those who are infectious, and initiating standard therapy; there is evidence of the value in treating LTBI in elderly residents of nursing homes to prevent future outbreaks and that treatment of LTBI can reduce the risk for death due to progression to active TB. CMS Ex. 32, at 5-6; CMS Ex. 33, at 6; CMS Ex. 41, at 86; CMS Ex. 53, at 60, 70.
- CDC recommended strategies for controlling TB in the United States include identification of people with LTBI that are at risk for progression to active TB and treatment with an effective drug regimen. CMS Ex. 30, at 16; CMS Ex. 53, at 17. The preferred treatment for LTBI is nine months of isoniazid (INH), but other treatment regimens are characterized as acceptable alternatives. CMS Ex. 30, at 18; CMS Ex. 41, at 55, 86.
- The responsibility for TB control and prevention in the United States rests upon public health officials, including federal, state, county, and local public health agencies. CMS Ex. 53, at 22.
- The primary responsibility for ensuring the quality and completeness of all TB-related services rests with the jurisdictional health agency. CMS Ex. 53, at 25; P. Ex. 4, at 2, 7; P. Ex. 5, at 1-2.

C. Maryland Regulations and Guidelines

The Code of Maryland Regulations (COMAR) in effect at the time of the survey addressed a number of

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processes involving SNFs, including Medical Director Duties and TB control, and identified actions for both health care providers and health officers.⁷ See COMAR, Department of Health, Diseases, Communicable Diseases and Related Conditions of Public Health Importance § 10.06.01 (2017); Department of Health, Hospitals, Comprehensive Care Facilities and Extended Care Facilities, Medical Director Duties § 10.07.02.11-1 (2017), and Infection Control Program (ICP) § 10.07.02.21 (2017). These regulations incorporate CDC *Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Facilities* (Morbidity and Mortality Weekly Report (MMWR) 1994; Vol. 43/No. RR-13).⁸ COMAR § 10.07.02.01-1(B)(1).

A health officer is required to recommend appropriate treatment for LTBI for contacts of communicable TB as well as provide for supervised treatment of LTBI for children under four (4). *Id.* § 10.06.01.21(B)(2)-(3); see CMS Ex. 38, at 19. A facility Medical Director is responsible for overall coordination, execution, and monitoring of physician services, and shall perform other essential duties related to clinical care and physician practices, including serving as a liaison with local health officials and public health agencies that have policies and programs

⁷ COMAR section 10.06.01.02(13) defines “health officer” as the health officer in each of the 23 counties and the Commissioner of Health in Baltimore City, or the duly designated representative of the health officer, or both.

⁸ We note that this version of the CDC Guidelines was not the current version. The CDC updated the Guidelines in 2005. See CMS Ex. 41, *Guidelines For Preventing The Transmission of Mycobacterium tuberculosis In Health-Care Settings*, (MMWR 2005; Vol. 54/No. RR-17).

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that may affect the facility's care and services to residents. *Id.* § 10.07.02.11-1(A)(1), (G)(3); *see* CMS Ex. 38, at 13-14. A SNF is required to develop written policies, consistent with COMAR, to govern the nursing care and related medical or other services it provides, including Infection Control and TB surveillance. *Id.* § 10.07.02.09(A)(15)-(16); *see* CMS Ex. 38, at 7. A facility's ICP shall include monitoring of the health status of all residents to determine if the residents are free from communicable TB. *Id.* § 10.07.02.21-2(A). Additionally, a facility shall assess residents for TB according to CDC Guidelines, perform a yearly symptom review and assess and manage a resident with a history of previous positive TB skin test, previous history of active TB, or positive skin test conversion⁹ in accordance with CDC Guidelines. *Id.* § 10.07.02.21-2(B)(1), (4)-(5).

The Maryland Department of Health and Mental Hygiene issued Guidelines for Prevention and Treatment of TB in 2007. CMS Ex. 39. These Guidelines reference the 2005 version of the CDC *Guidelines For Preventing The Transmission of Mycobacterium tuberculosis In Health-Care Settings*, 2005. MMWR 2005; Vol. 54/No. RR-17. *See* CMS Ex. 39, at 8, 45. These Guidelines address the roles of both the local health departments and providers, and state that limited public health resources should be allocated and prioritized, and list activities in descending priority order, with three levels. *Id.* at 10. Treatment of LTBI is

⁹ "Skin test conversion" is a change in the result of a skin test for TB that is interpreted to indicate a change from being uninfected to infected. A conversion is presumptive evidence of new TB infection and poses an increased risk for progression to active TB disease. *See* CMS Ex. 40, at 41.

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listed in both the second and third level, depending on the individual's risk. *Id.* at 11-12 (Table 4). The Maryland Guidelines also include:

- It is the responsibility of the local health department to identify, evaluate promptly, and ensure an appropriate course of treatment is prescribed and completed for all people suspected of having active TB. *Id.* at 10.
- A private provider undertaking to treat one with active TB is undertaking a public health function that includes prescribing an appropriate treatment regime and ensuring adherence to that regime until treatment is completed. *Id.*
- A decision to test is a decision to treat, including recent contacts exposed to TB infection and residents of SNFs/nursing facilities (NFs). *Id.* at 12-14.
- Treatment should be targeted to high-risk groups regardless of age, including the recently infected and those in SNFs/NFs. *Id.* at 19.
- The purpose of treating LTBI is to reduce the chance an individual with LTBI progresses to active TB. *Id.*
- Individuals found to have a positive skin test should be examined by a provider to rule out active TB disease and be evaluated for treatment of LTBI. The evaluation consists of TB symptom review, CXR, and testing and evaluation of other medical conditions. *Id.*
- Either INH or rifampin is used for treatment of LTBI. *Id.* at 20-21.

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Case Background¹⁰

Petitioner operates a long-term care facility in Takoma Park, Maryland that participates in Medicare as a SNF. The factual basis of this appeal is nearly undisputed and involves the occurrence of active TB and LTBI, involving both staff members and residents, in Petitioner’s facility in 2015 and 2016.

A. Petitioner’s written policy concerning TB Management

Petitioner’s written infection control policy (ICP) included policies and procedures specific to TB Management. P. Ex. 6.¹¹ The policy’s stated purpose was “[t]o reduce the risk for [TB] among patients” and “[t]o provide appropriate management post exposure.” *Id.* at 1. The practice standards for screening indicated that all residents are tested upon admission. *Id.* ¶ 1.1. The standards for post exposure indicated that when TB is identified, “notify the state Health Department and follow its recommendations for investigation and follow-up”; “[i]nvestigate to identify if any patients or employees have been exposed”; and “[f]ollow Tuberculosis Post Exposure procedure to determine treatment

¹⁰ This section is drawn from the ALJ Decision and the record before the ALJ and provides context for the issues Petitioner raises on appeal.

¹¹ P. Ex. 6 contains excerpts from the ICP. This policy and its procedures were mandated by Genesis HealthCare, who managed and operated Petitioner, along with other SNFs across the U.S during the time period at issue. To avoid confusion, we will refer to these as Petitioner’s policy and procedures. See Tr. at 849 (Testimony of Genesis Sr. Vice President of Medical Affairs (Sr. VP of Medical Affairs)).

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needed for patients.” *Id.* ¶¶ 2.1-2.2.1 (emphasis omitted).

The TB screening procedures specify initial testing frequency and what to do if both the first and second tests are negative (no further evaluation is needed); or positive (obtain a CXR and medical evaluation); and observe for signs and symptoms of TB (if any present, initiate medical evaluation). *Id.* ¶¶ 2-2.3. These procedures also specify the process for residents with a particular history, including a written history of a positive skin test, residents who have a history of the BCG vaccination, residents with necrotic or anaphylactic response to the skin test, and those who refuse the skin test. *Id.* ¶¶ 3.1-3.4. Finally, it addresses screening documentation. *Id.* ¶ 5.

The post-exposure procedures for residents specify what to do as soon as TB exposure is identified and how to handle residents with and without a written history of a positive skin test. *See id.* ¶¶ 1-4. In either case, obtaining a CXR and medical evaluation is required, and if negative for active disease, the resident is to be medically evaluated for prophylaxis. *Id.* ¶¶ 3.5, 4.1.2. Finally, the post exposure procedures address documentation, indicating that skin test administration and results are documented in the Medication Administration Record (MAR) or PCC [“PointClickCare” electronic record system implemented by Genesis], and interventions and follow-ups such as a CXR, are documented in nurse’s notes. *Id.* ¶¶ 5.1-5.2.

B. TB Incidents in 2015 and 2016

In 2015, two of Petitioner’s staff members were diagnosed with active TB by the Montgomery County,

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Maryland Department of Health and Human Services (hereinafter the county) on different dates. On or about March 10, 2015, the county initially notified Petitioner that staff member #1, who worked in the laundry, “is under my care and is **not cleared** to return to work.” ALJ Decision at 14; P. Ex. 1 (emphasis added). The initial letter did not reveal that staff member #1 had active TB, but Petitioner learned of the diagnosis approximately two months later from the employee’s leave paperwork indicating the employee had active TB. *Id.*; see also CMS Ex. 14, at 36. The case of staff member #1 is referred to as an “index case” by the parties and their respective expert witnesses. ALJ Decision at 14. On April 27, 2015, Petitioner learned staff member #2 was being treated for active TB and had been hospitalized from April 8-21, 2015, again from leave paperwork submitted by the employee.¹² CMS Ex. 14, at 37. On May 7, 2015, the county reached out to Petitioner’s infection control nurse (ICRN), requesting that the facility provide the “housekeeping/laundry” staff members with the number for the county to “make an appointment with them for assessment.” *Id.* at 36.

While some details are not fully developed in the record, on May 13, 2015, the county communicated to Petitioner that staff members #1 and #2 had been diagnosed with active TB and that a former resident who had been hospitalized in March of 2015 and subsequently passed away in April of 2015 (while still hospitalized), was found to have active TB at the time of death. See CMS Ex. 13, at 14; ALJ Decision at 14

¹² On May 18, 2015, the county Medical Director notified Petitioner that employee #2 “is currently under my care and is **cleared** for work.” See CMS Ex. 14, at 35 (emphasis added).

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(citing Tr. at 987-92); Petitioner's Proposed Finding of Fact (PPFF) ¶ 78; CMS Proposed Findings of Fact (CPFF) ¶ 21. The county Nurse Administrator for TB control contacted Petitioner's facility administrator to set up a meeting to discuss TB contact investigation and response to the situation. CMS Ex. 44, ¶ 2; Tr. at 466, 986. That meeting took place on May 15, 2015, and both the county Nurse Administrator and the county Case Manager visited Petitioner and met with its staff to provide guidance regarding the TB contact investigation process. CMS Ex. 14, at 40-41, 45; CMS Ex. 44, ¶ 2; *see also* P. Ex. 7 (list of meeting attendees).

The primary purpose of the county's meeting with Petitioner's staff was "to provide direction . . . about how to perform the contact investigation for staff and residents following active [TB] exposure." CMS Ex. 44 ¶ 2. County personnel explained to staff that the SNF was at high risk for TB transmission because it is a congregate setting, and further indicated that because Petitioner's staff were responsible for the direct care and treatment of its residents, Petitioner's staff would be responsible for testing its residents for TB and for follow up treatment. *Id.* at ¶¶ 2-3. County personnel testified that during that meeting they reviewed general guidance regarding prophylactic treatment to individuals with LTBI, informed Petitioner it was responsible for providing prophylactic treatment, and recommended that anyone with a positive skin test or QFT-G test, and active TB ruled out, receive prophylactic treatment unless contraindicated. *See* Tr. at 486-491, 569-570, 575. Petitioner's staff indicated they would handle all the TB skin testing of residents and requested assistance from the county for resi-

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dents for whom a QFT-G blood test was recommended.¹³ *Id.* Generally, the contact investigation involves a series of two skin tests, eight weeks apart, for anyone who has not already had a positive skin test (all residents are tested on admission to the SNF). Anyone with a positive skin test or positive QFT-G test would then receive a CXR to rule out active TB. Tr. at 565-569.

Over the ensuing weeks, the first round of skin testing was done for Petitioner's staff and residents, and CXRs were taken as needed. Again, the details are somewhat imprecise, but at least 19 residents had positive skin tests and negative CXRs.¹⁴ *See* P. Exs. 9, 11, 13; *see also* ALJ Decision at 15 n.13. No residents were found to have active TB. *Id.* Petitioner's ICRN and the county staff agreed to hold off with any LTBI prophylactic treatment until after the second round of testing. *See* ALJ Decision at 15 (citing Tr. at 585-87, 633-34, 1065; PPFF ¶ 111; CPFF ¶ 32). In August 2015, the second round of skin testing was initiated for all residents with negative results in the first round. Out of 40 residents tested, six had posi-

¹³ TB skin testing is interchangeably referred to as PPD and TST. At the time of this contact investigation, the county administered the QFT-G test. *See* Tr. at 574-575.

¹⁴ The ALJ discussed the discrepancies in the number of residents who tested positive during the 2015 testing. *See* ALJ Decision at 15 n.13. The ALJ ultimately determined that there was no need to resolve the disparate numbers as there were at least 19 residents with positive skin tests and/or QFT-G and negative CXRs and the absence of consistent detailed evidence did not prevent a decision in the case. *Id.* We agree that discrepancies in the numbers in both the 2015 and 2016 testing does not prevent us from reviewing that decision.

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tive results, but all had negative CXRs. P. Ex. 15. Additionally, a few residents with positive skin tests and negative CXRs in round one had passed away, been discharged, or transferred out of the facility before the second round of testing. *See* P. Ex. 15, at 14; CMS Ex. 28, at 2. The county had drawn blood for QFT-G testing for some, but not all, of the residents who required it. P. Ex. 15, at 13-14.

One resident, R4, being evaluated for a possible kidney transplant, tested positive on the skin test and QFT-G during round one of the 2015 testing. P. Ex. 11, at 3; P. Ex. 20, at 1; CMS Ex. 8, at 36-37. On September 17, 2015, Petitioner's ICRN texted the county Case Manager, inquiring about treatment advice for dialysis patients. P. Ex. 18, at 1. The Case Manager's response indicated "we have no dr right now. i will have to check with dr Walsh when he comes next week to read X-rays." *Id.* at 2. In October of 2015, while undergoing testing for the kidney transplant, R4's bloodwork again tested positive for LTBI. P. Ex. 20, at 2; *see also* Tr. at 1060. The transplant evaluation physician prescribed INH and Vitamin B6 (prophylactic treatment).¹⁵ P. Ex. 20, at 1-2. On November 5, 2015, Petitioner's ICRN again texted the county Case

¹⁵ Petitioner's ICRN testified that R4's prescribed prophylactic treatment was administered as ordered, beginning in 2015. Tr. at 1061. However, the documentary evidence in the record states R4's "start date 10/30/15 [INH] 300 mg QD and B6 50 mg QD" and "started INH + Vit 6 10/15 completed 10/3/16." *See* P. Ex. 14, at 4-5, 10 (R4's entire clinical record is not in the record). The ALJ noted entries for prescriptions for INH and vitamin B6 dated June 22, 2016—but it was not clear from the physician's order sheet whether the order was new or had been in place since 2015. ALJ Decision at 16; *see also* CMS Ex. 8, at 29, 31.

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Manager, indicating a fax with the updates on the dialysis patient would be forthcoming, and asked again about scheduling the last few residents for QFT-G blood draws. P. Ex. 18, at 4; P Ex. 20, at 1. The county Case Manager responded that perhaps the blood draws could be done the following week since it required coordination with lab personnel, and asked if “[Petitioner’s Medical Director] put residents on prophylaxis?” P. Ex. 18, at 4. The ICRN replied that Petitioner had a new medical director and “[n]othing has been started with the residents. We will need to coordinate process.” *Id.* at 4-5. The county Case Manager replied that she too had a new medical director and “maybe we can meet one afternoon and figure out a plan.” *Id.* The last communication in the record between the ICRN and county Case Manager is another text sent by the ICRN, over two months later, on January 26, 2016, “[w]ondering what the plans are for Sligo” and indicating that staff member #2 had stopped by the facility but only got as far as the front lobby. *Id.* at 6. The Case Manager replied, “plan to meet with you soon to see where we are.” *Id.* at 7.

TB testing and the administration of prophylactic medication for LTBI was regularly discussed among Petitioner’s staff and management at the Quality Assurance (QA) meetings from August 2015 through January 2016. ALJ Decision at 16 (citing PPFF ¶¶ 125, 128-29; CPFF ¶¶ 43-47). Petitioner’s Administrator testified that the QA Committee continued to discuss the matter after January 2016, but acknowledged that the Committee Minutes did not include this topic. PPFF ¶ 130; CPFF ¶ 48. In May 2016, Petitioner’s staff did an annual assessment of residents who had previously tested positive for exposure to TB

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in 2015 and found no one exhibited signs or symptoms of active TB. ALJ Decision at 16 (citing PPFF ¶ 130; P. Ex. 21).

On June 4, 2016, R1 informed a member of the nursing staff of coughing with chest pain. P. Ex. 10, at 1. R1 had tested positive on the skin test during round one of TB testing in 2015 and previously had a negative CXR, but no prophylactic treatment. CMS Ex. 5, at 29-30, 36; Tr. at 1025-1026. R1's attending physician ordered a CXR, which showed modest left lower lobe and right upper lobe patchy infiltrates. CMS Ex. 5, at 17. The attending physician diagnosed R1 with bronchitis and prescribed antibiotics, nebulizer treatments and cough medicine. *Id.* at 2. On August 8, 2016, R1 was coughing up blood and was transferred to a hospital. *Id.* Nothing in the record indicates that anyone at Petitioners facility identified this as a possible symptom of active TB. At the hospital, R1 tested positive for active TB. *See* PPFF ¶ 183; CPFF ¶ 55; *see also* CMS Ex. 1, at 18. R1's diagnosis resulted in Petitioner and the county again testing all residents for TB. *See* P. Ex. 14; ALJ Decision at 17. The 2016 testing revealed no cases of active TB, but 23 residents were found to have LTBI, 17 of whom were identified in the 2015 testing. The county medical director prescribed prophylactic treatment (INH and Vitamin B-6). *See* P. Ex. 27; *see also* Tr. at 1069-70. There is no dispute among the parties that the only resident identified in 2015 as having LTBI who received prophylactic treatment before September of 2016 was R4, which the county played no role in. ALJ Decision at 16 (citing PPFF ¶¶ 132, 134-135, 137, 139, 158; CPFF ¶ 40-41).

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C. 2016 complaint survey and the CMP

On September 27, 28 and October 6, 2016, the Maryland Department of Health and Mental Hygiene, Office of Health Care Quality (state agency) conducted an on-site “complaint survey” of Petitioner’s facility.¹⁶ CMS Ex. 1; CMS Ex. 19, at 1. A “complaint survey” is a survey “conducted on the basis of a substantial allegation of noncompliance.” 42 C.F.R. § 488.705. A “substantial allegation of noncompliance” is defined as “a complaint from any of a variety of sources (such as patient, relative, or third party), . . . that would, if found to be present, adversely affect the health and safety of patients or residents and raises doubts as to a provider’s or supplier’s compliance with any Medicare condition of participation, condition for coverage, condition for certification, or requirements.” *Id.* § 488.1. Additional survey activities involved interviews of county staff. *See* CMS Ex. 1, at 12-13, 19. On December 12, 2016, the state agency conducted a revisit survey and found the facility was in substantial compliance but identified deficiencies that posed no actual harm with potential for minimal harm. *See* CMS Ex. 19, at 35-44.

The initial 2016 survey resulted in citations for multiple deficiencies, only one of which is the subject of this appeal, the violation of section 483.65, which states (in part) that a SNF “must establish and maintain an infection control program designed to provide a safe, sanitary and comfortable environment and to

¹⁶ There were two different complaints filed, only one of which dealt with the occurrence of TB in the facility. *See* CMS Ex. 23. No aspects of the other complaint are part of this appeal.

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help prevent the development and transmission of disease and infection.” CMS Ex. 1, at 5-15. The basis for that deficiency citation was a finding that Petitioner had failed to “ensure timely follow up of the treatment and management of multiple residents who were identified at risk for exposure to a serious infectious disease [TB] [and] . . . failed to record in residents’ clinical records the rationale for treatment/non treatment for the potential exposure to [TB].” *Id.* at 7. The survey further found that Petitioner’s violation of section 483.65 had placed residents in immediate jeopardy.

There was no date listed for when immediate jeopardy level noncompliance began, but removal of the conditions that posed immediate jeopardy was confirmed by the resurvey on October 6, 2016. *Id.* at 7-8; *see also* CMS Ex. 19, at 1. On October 19, 2016, the state agency informed Petitioner that an immediate per-instance CMP of \$8,000 was imposed by the state agency for the deficiency alleging noncompliance with section 483.65. CMS. Ex. 19, at 2. Additionally, Petitioner was informed of the opportunity to request a hearing on the decision to impose the CMP or to pursue Informal Dispute Resolution (IDR) at the state level in accordance with section 488.331. *Id.* at 3-4. Finally, the state agency indicated that it would recommend CMS terminate Petitioner’s provider agreement on April 6, 2017, if substantial compliance was not achieved by that time, and further indicated that if substantial compliance was not achieved by January 6, 2017, CMS would be required to deny payments for new admissions (DPNA). *Id.* at 2.

On October 28, 2016, in accordance with the state agency’s guidance, Petitioner requested IDR for the cited deficiency alleging noncompliance with section

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483.65, including the scope and severity of the deficiency. CMS Ex. 14. On December 13, 2016, the IDR results, which upheld the deficiency but modified the text of the citation, were provided to Petitioner. CMS Ex. 36, at 1, 16.¹⁷ On January 31, 2017, CMS concurred with the state agency's survey findings, determined the immediate jeopardy began on June 14, 2016, and imposed a \$12,541 per-day CMP for the immediate-jeopardy period (June 14 through October 5, 2016) and a \$330 per-day CMP for the remaining period of noncompliance (October 6 through December 11, 2016). CMS Ex. 20, at 1-5.

D. Proceedings before the ALJ

On March 20, 2017, Petitioner timely requested an ALJ hearing, contesting only the finding of "immediate jeopardy" noncompliance of section 483.65, and the associated remedies CMS imposed as a result of that finding. Req. for Hrg. (RFH) at 2.¹⁸

¹⁷ The notice does not indicate what the modifications were, but a comparison of the text in the original SOD and the version attached to the IDR report reveals the last paragraph of the original text was removed. It stated, "There is no documented evidence that the facility reached out to the local health department/CD&E/TB staff, except as indicated during some of the monthly Quality Assurance meeting documentation when 'waiting for the local health department follow up.'" Compare CMS Ex. 1, at 14-15 with CMS Ex. 36, at 14.

¹⁸ The RFH indicates that Petitioner requested Independent Informal Dispute Resolution (IIDR) to contest the cited deficiency, which was pending as of the date of the RFH, but further stated that if the IIDR process causes CMS to withdraw the CMP at issue, Petitioner would dismiss the appeal. RFH at 2. The record does not contain that request, but it does contain the result of the IIDR, issued on March 29, 2017, substantiating the citation but indicating the reviewer determined that August 4,

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The evidence offered by the parties in this case was voluminous; including excerpts from eight residents' clinical records; Petitioner's TB Management policy; memoranda from Petitioner's Director of Nursing (DON), ICRN, and a "statement" from the prior medical director documented in the form of a memo by the Genesis Sr. VP of Medical Affairs; documents from both the 2015 and 2016 contact investigations; information regarding the QA Committee meetings; communications between members of Petitioner's staff and the county; excerpts from various CDC and Maryland TB Guidelines and COMAR; survey and post-survey CMP documents and enforcement history; excerpts from CMS Pub. 100-07, State Operations Manual (SOM) (requested by the ALJ); and curricula vitae (CVs), reports, and declarations from expert witnesses for each party offered as written direct testimony. CMS also offered declarations from the surveyor, the county Nurse Administrator, and deposition testimony from its expert witness.

The parties stipulated to the following facts:

- Petitioner is a SNF located in Takoma Park, Maryland and, at the time of the pertinent events at issue here, participated in the Medicare and Medicaid programs.
- On October 6, 2016, the state agency conducted a survey at Petitioner's facility, following which it cited certain deficiencies, including one deficiency at 42 C.F.R. § 483.65 (infection control) at scope and severity of "K," based on the sur-

2016, should be the start date for the immediate jeopardy determination. CMS Ex. 13, at 1, 14.

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vey team's finding of a pattern of deficient practice. As a result of the survey findings, the survey team called "immediate jeopardy" on October 6, 2016 at 6:10 P.M. based on the infection control deficiency. The Immediate Jeopardy was abated the same day at 10:30 P.M.

- The state agency sent Petitioner a copy of a SOD from the October 6, 2016 survey (CMS Exhibit 1).
- CMS concurred with the state agency survey findings and the determination of Immediate Jeopardy. As a result, on January 31, 2017, CMS sent Petitioner a Notice regarding the findings of the October 6, 2016 survey (CMS Notice). CMS Ex. 20, at 1.
- CMS imposed a "per diem" CMP in the amount of \$12,541 per day for the 114 days beginning June 14, 2016, through October 5, 2016 (\$1,429,674); and a per-diem CMP in the amount of \$303 for the 67 days beginning October 6, 2016, through December 12, 2016¹⁹ (\$20,301), a total of \$1,449,975.
- CMS did not impose a DPNA or provider agreement termination action.
- CMS also provided that Petitioner would be disqualified from offering a nurse aide training and competence evaluation program

¹⁹ As the ALJ noted, CMS determined that Petitioner returned to substantial compliance effective December 12, 2016, thus ending the accrual of the CMP effective December 11, 2016. ALJ Decision at 3 n.2. Thus, as the ALJ also noted, "[t]he parties incorrectly stipulated that the CMP . . . ran through December 12, 2016." *Id.*

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(NATCEP) for a period of two years. Petitioner did not operate a NATCEP at the time, and so that remedy is not at issue here.

- CMS's determination that Petitioner was out of compliance with the non-immediate jeopardy deficiencies is administratively final as is CMS's imposition of a \$303 per day CMP for the 67 days from October 6, 2016, through December 11, 2016.

Joint Settlement Status Report, Joint Stipulation of Undisputed Facts, and Joint Statement of Issues Presented for Hearing ¶ B.

The parties further agreed that the issues were (1) whether the deficiency for section 483.65 constituted noncompliance (as defined at 42 C.F.R. § 488.301); (2) whether CMS's immediate jeopardy determination was clearly erroneous; and (3) whether the \$12,541 per day CMP for 114 days (immediate jeopardy period) was reasonable. *Id.* ¶ C.

E. ALJ Decision

The ALJ issued a decision on October 23, 2020, finding Petitioner was not in substantial compliance due to violations of multiple participation requirements established by 42 C.F.R. § 483.65. ALJ Decision at 1. The ALJ Decision includes extensive summarized witness testimony, necessary because:

Although the parties agreed to most of the relevant facts, they presented witness testimony rather than simply stipulating to the undisputed facts. In this case, the witness testimony is particularly helpful for me to better understand the extremely complex issues related to TB, its identification, and

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treatment. For that reason, a summary of the relevant testimony is included in this decision, with weight and credibility determinations noted. No significant issues of credibility are identified, and all witnesses generally provided credible testimony except where noted. However, as addressed for certain witnesses, the weight of witness testimony is significantly affected by knowledge of the facts, including CDC guidance and Maryland law, which is set forth in some detail in this decision. Witness testimony is also summarized here as my findings of what they testified to. This is particularly necessary in this case given a significant number of errors and omissions in the transcript due to the inadequacy of microphones used during this video conference hearing, and the need to clarify with witnesses when questions and responses were muddled or confused.

Id. at 20 n.15.

The ALJ made findings of fact which included:

- In May and August 2015, Petitioner's staff and the county conducted two rounds of TB testing of residents who might have been exposed to an employee with active TB. At least 19 or 20 residents had positive results. CXRs showed that none of the residents had active TB in 2015. It is undisputed that a positive TB test and a negative CXR shows the individual has LTBI.
- Petitioner concedes that a resident with a positive TB test and a negative CXR should be treated at some time.

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- R4, identified as having LTBI in 2015, was started on treatment beginning on or about October or November 2015, pursuant to an order from a physician (not affiliated with Petitioner) in preparation for a possible kidney transplant.
- There is no dispute that the remaining 18 to 19 residents identified as having LTBI in 2015, including R1, received no treatment for LTBI until September 2016.
- Petitioner's TB infection control policy specifically required that someone identified with a positive TB test and a negative CXR be referred for medical evaluation for treatment.
- Unrebutted evidence shows that five percent of all persons with LTBI will convert to active TB infection within two years of exposure to TB.
- If not treated properly, active TB can be fatal, and five percent of patients diagnosed in the U.S. each year with active TB are either dead when diagnosed or die during treatment.
- Residents and staff of congregate settings such as long-term care facilities are among those at highest risk for exposure and infection.
- CDC guidance stresses that the treatment of LTBI is essential to "control and eliminate TB" because it substantially reduces the risk of progressing to active TB.
- The ALJ inferred, based on the known risks associated with TB, that Petitioner's policy, not alleged to be defective, requires prompt action by Petitioner's staff for all steps required for handling a TB outbreak.
- All but one resident identified as having LTBI in 2015 were never evaluated for treatment until after R1 was diagnosed with active TB; and

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none were referred to their primary care physicians for evaluation for treatment.

- There is no dispute that a decision was made to delay prophylactic treatment of the LTBI cases until after the second round of testing of residents was completed in 2015. There is no evidence of any agreement between Petitioner's staff and the county or direction from the county as to how long treatment for LTBI could be delayed.
- There is no evidence that the risk posed to residents due to the delay was assessed by either the county or Petitioner. There is also no evidence that any physician was involved in the decision to delay treatment for LTBI.

ALJ Decision at 34-36.

Petitioner alleged there was a conflict of interest because the surveyor and the county health employees worked for the same state agency. P. Br. at 6-7 n.6, 36; P. Rep. Br. at 4 n.1. The ALJ explained that any alleged conflict was immaterial because his review was de novo and his decision was not based on the surveyor's testimony or observations in the SOD, but on the testimony of the other witnesses, documents other than the SOD, and the undisputed facts. ALJ Decision at 50. The ALJ noted that Petitioner conceded that the Board has found that allegation of defects in the survey process are immaterial when there is an otherwise appropriate basis for finding noncompliance. *Id.* (citing P. Rep. Br. at 4, n.1). The ALJ made four conclusions of law regarding the noncompliance

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citation at the level of immediate jeopardy, and the reasonableness of the CMP based on that citation;²⁰

- CMS established a prima facie case that Petitioner was not in substantial compliance with 42 C.F.R. § 483.65. *Id.* at 9.
- Petitioner did not meet its burden to show it was in substantial compliance with 42 C.F.R. § 483.65 during the period June 14 through December 11, 2016. *Id.*
- Petitioner failed to show that the determination or duration of immediate jeopardy was clearly erroneous. *Id.* at 50.
- The CMP for the period of immediate jeopardy was reasonable. *Id.* at 58.

We will discuss the ALJ's findings and conclusions in more detail in our analysis.

F. Proceedings before the Board

Petitioner timely requested Board review of the ALJ Decision, asserting the ALJ's determination to uphold the deficiency for failure to comply substantially with 42 C.F.R. § 483.65 and the corresponding per-day CMP for the immediate-jeopardy period (June 14, 2016 through October 5, 2016) as reasonable must be set aside. Request for Review (RR) at 1, 24. Petitioner asserts the ALJ's arbitrary and capricious

²⁰ As Petitioner did not request review of the noncompliance cited as violations of 42 C.F.R. §§ 483.20(k)(3)(1), 483.35(i), and 483.70(h)(4), or the \$303 per day CMP associated with those citations, the ALJ made two additional conclusions of law, finding those citations and the associated CMP administratively final, and that the \$303 per day CMP is not subject to further review for reasonableness. ALJ Decision at 9.

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creation of an ad hoc requirement based on an “*inference* of an *unwritten* obligation” for its staff to assume certain obligations that Maryland law specifically assigns to the county; as well as completely new obligations, and “imported those *implied* obligations into then Section 483.65 as regulatory requirements.” *Id.* at 24-25. Petitioner also asserts the ALJ Decision is not supported by the record²¹ and some of the findings of fact are inconsistent with the plain language of CMS’s Guidelines, including the ALJ’s minimization of the alleged conflict of interest.²² *Id.* at 27, 32-33.

²¹ Petitioner’s argument relies on the proposition that the only basis for noncompliance could be the county sending treatment orders in 2015, and Petitioner receiving, but not implementing, those orders. Without that, it asserts that any basis for noncompliance is dependent on an ad hoc regulatory obligation. The ALJ found credible evidence that the county “sent treatment recommendations to Petitioner’s medical director. However, there is also credible evidence, sufficient to overcome any presumption of receipt, that the treatment recommendations were not received.” ALJ Decision at 39. The ALJ’s determination of noncompliance did not turn on whether Petitioner ever received treatment recommendations from the county, concluding that receipt or non-receipt of recommendations was immaterial; Petitioner would be no less liable for failure to follow its infection control policy in either case. *Id.* at 39-40; *see also* n.21.

²² As the ALJ relied on evidence other than the surveyor’s testimony or related observations in the SOD, and made credibility determinations on all the witnesses, we need not address the conflict argument any further. *See Avon Nursing Home*, DAB No. 2830, at 11-12 (2017) *citing Sunshine Haven Lordsburg*, DAB No. 2456, at 21 (2012), *aff’d in part and transferred*, *Sunshine Haven Lordsburg v. U.S. Dept. of Health & Human Servs.*, 742 F.3d 1239 (10th Cir. 2014) (noting that the ultimate issue is not whether the survey was performed correctly but whether “the evidence as it is developed before the ALJ supports” CMS’s independent “finding of non-compliance” under the relevant participation requirements) (internal quotation marks omitted);

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Finally, Petitioner asserts that there is no basis for the duration of the noncompliance. *Id.* at 36.

CMS asserts there is no dispute that TB is an infection covered by 42 C.F.R. § 483.65, and Petitioner's TB Post Exposure procedure states if a resident has a positive skin test and a negative CXR (which identifies the resident as having LTBI), the infection control plan called for evaluation for prophylaxis and that did not happen. CMS Br. at 16-17 (citing P. Ex. 6; Tr. at 1032, 1077). CMS alleges that by failing to implement its own infection control policy, Petitioner ignored its duty to "help prevent the development and transmission of disease and infection" as required by section 483.65. *Id.* at 18. CMS denies that Petitioner's obligation to implement its own TB infection control policy is an "ad hoc regulatory obligation" but rather a clearly defined and well-known regulatory requirement. *Id.* at 20. Finally, CMS asserts that Petitioner is legally responsible for implementation of its infection control policies and procedures, regardless of what the county did or did not do. *Id.* CMS further asserts that Petitioner did not show that the finding of immediate jeopardy, or the duration of immediate jeopardy, was clearly erroneous. *Id.* at 27-33. CMS asserts that the Board should uphold the ALJ's decision. *Id.* at 33.

see also *Lifehouse of Riverside Healthcare Ctr.*, DAB No. 2774, at 13 (2017); *Blossom South Nursing & Rehab. Ctr.*, DAB No. 2578, at 19 (2014) (the Board defers to ALJ findings on weight and credibility of witness testimony absent a compelling reason to do otherwise); *see, e.g., Woodland Oaks Healthcare Facility*, DAB No. 2355, at 7 (2010). Petitioner has shown no such clear error or other compelling reason here.

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Petitioner’s reply brief asserts the evidentiary premises for CMS’s arguments are flawed; CMS misstates the language of Maryland law; and that CMS never identified any regulatory basis for the sanction imposed. *See* P. Rep. Br. at 1-2, 7, 15, 17. Petitioner concludes by reasserting its position that its “staff did what the County Health Department instructed them to do, which was the extent of [its] obligations under both then-Section 483.65, State law, and its own TB Policy.” *Id.* at 20.

On July 2, 2024, Petitioner moved for remand and a refund of its CMP based upon the Supreme Court decision of *Securities and Exchange Commission v. Jarkesy*, 144 S. Ct. 2117 (2024). P. Mot. for Remand, & for Refund of CMP (P. *Jarkesy* Mot.). On July 12, 2024, CMS filed an opposition to Petitioner’s motion. Opp. to Mot. for Remand, & for Refund of CMP (CMS *Jarkesy* Opp.). By letter dated July 22, 2024, the Presiding Board Member notified Petitioner of the opportunity to submit a reply to CMS’s response within 15 days after receipt of the notice. Not. of Opportunity to Reply at 1. Petitioner filed a timely reply. P. Reply to CMS *Jarkesy* Opp. (P. *Jarkesy* Reply).

This Decision addresses Petitioner’s challenges of the ALJ Decision that we deem have merit as to the legal and factual sufficiency of the ALJ Decision involving Tag F441, and Petitioner’s arguments concerning *Jarkesy*. As explained below, we affirm the ALJ’s Decision, and deny Petitioner’s motion for relief pursuant to *Jarkesy*.

Standard of Review

In cases proceeding under 42 C.F.R. Part 498, the Board’s standard of review on a disputed factual issue

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is whether the ALJ decision is supported by substantial evidence; the standard of review on a disputed issue of law is whether the ALJ's decision is erroneous. *See Duke Ahn, MD.*, DAB No. 3093, at 7 (2023); *see also* Guidelines—Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's or Supplier's Enrollment in the Medicare Program (Guidelines), accessible at <https://www.hhs.gov/about/agencies/dab/different-ap-peals-at-dab/appeals-to-board/guidelines/enrollment/index.html?language=en>.

“Substantial evidence” means “such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.” *Consulate Healthcare of Jacksonville*, DAB No. 3119, at 11 (2023) (citing *Richardson v. Perales*, 402 U.S. 389, 401 (1971) (quoting *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938)). “The ‘substantial evidence’ standard is deferential.” *Glenoaks Nursing Ctr.*, DAB No. 2522, at 6 (2013). “Under the substantial evidence standard, the Board does not re-weigh the evidence or overturn an ALJ's choice between two fairly conflicting views of the evidence; instead, the Board determines whether the contested finding could have been made by a reasonable fact-finder taking into account whatever in the record fairly detracts from the weight of the evidence that the ALJ relied upon.” *Douglas Bradley, MD.*, DAB No. 2663, at 5 (2015) (internal quotation marks, brackets, and citations omitted); *see also Golden Living Ctr.-Frankfort*, DAB No. 2296, at 9-10 (2009), *aff'd*, 656 F.3d 421 (6th Cir. 2011).

Analysis

Having reviewed the entire record and considered Petitioner's arguments along with CMS's responses to

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those arguments, we affirm the ALJ Decision because substantial evidence supports the ALJ's findings and conclusion that Petitioner was not in substantial compliance with 42 C.F.R. § 483.65.

A. The ALJ's conclusion that Petitioner was non-compliant with 42 C.F.R. § 483.65 is supported by substantial evidence and not legally erroneous.

Petitioner requests the Board set aside the findings of noncompliance and the imposition of the CMP because any adverse outcome in this case was the direct consequence of the county's failings, not an act or omission by Petitioner, much less an act or omission section 483.65 commanded or even addressed. RR at 40.

There is no dispute that Petitioner had an ICP for TB. The ALJ found that Petitioner's violation of section 483.65 was based on failing to ensure timely follow-up of the treatment and management of at least 19 residents identified as at risk for exposure to a serious infectious disease and on failing to record in the residents' clinical records the rationale for treatment or nontreatment. ALJ Decision at 38-39.²³ The ALJ further found that CDC and Maryland guidelines, and COMAR, establish the standard of care for LTBI in long-term care facility residents, and that care would involve the treatment of LTBI absent compelling contraindications, using INH. *Id.* at 41. Additionally, the ALJ found that Petitioner's policy and procedures

²³ The ALJ expressly indicated that alternative theories of liability offered by CMS at the hearing and in post-hearing briefs were not considered in concluding Petitioner was noncompliant with section 483.65. *See* ALJ Decision at 39.

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were not inconsistent with the standard of care defined by the applicable CDC and Maryland guidelines and regulations. *Id.* at 42. Accordingly, the ALJ held that Petitioner did not implement its TB management policies and procedures to prevent the development and spread of active TB by ensuring that residents identified as having LTBI were treated, unless contraindicated or refused, as required by section 483.65. *Id.* at 46 (“One of the responsibilities established by 42 C.F.R. § 483.65 is that Petitioner ‘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.’”).

For the reasons explained below, we affirm the ALJ’s conclusions that Petitioner was not in substantial compliance with 42 C.F.R. § 483.65.

1. Petitioner’s arguments concerning the ALJ’s creation of an ad hoc requirement as the basis for the sanction are not supported by the record.

Petitioner does not dispute that it must develop and maintain appropriate infection control policies and procedures, including policies and procedures for TB testing and control. However, Petitioner contends that the ALJ did not address the “context” for applying its TB Policy, since Maryland law, CDC guidance and its own TB Policy “specifically assign responsibility for certain aspects of TB control, including certain notification, testing, treatment, and followup tasks at issue here,[] to the [county].” RR at 2-3 (emphasis omitted).

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The ALJ summarized the essence of Petitioner’s argument as “because it did not receive recommendations from the county health department it should have no liability for its failure to control the TB outbreaks in 2015 and 2016, and the harm caused.” ALJ Decision at 45. The ALJ accepted, based on undisputed evidence in this case, that the county failed to complete blood testing of four residents; failed to ensure that Petitioner received the recommendations for treatment; and failed to ensure treatment was initiated in late 2015 or early 2016 for all residents identified as having LTBI. *Id.* at 46. Nevertheless, the ALJ concluded that the fact that the county did not promptly discharge its duties cannot be a defense for Petitioner’s failure to follow its infection control policy as required by section 483.65. *Id.* Petitioner disputes the ALJ’s characterization of its arguments as the county’s failures constitute a “defense” to the alleged noncompliance with its own regulatory obligation. RR at 3. Petitioner asserts the threshold evidentiary and legal questions are whether Petitioner’s staff “violated a clear agency directive, set forth in advance in any regulation, Interpretive Guidance, or anywhere else, to do something other than what they did.” *Id.* at 4.

Petitioner relies on the Sixth Circuit decision in *Golden Living Ctr. - Mountain View*, 832 F. App’x 967 (6th Cir. 2020), for the premise that because CMS never provided any notice that it might impose a sanction based on “implied obligations,” the imposition of sanctions based on such ad hoc interpretations is “arbitrary and capricious” under the Administrative Procedure Act (APA). *Id.* at 25-26.

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The noncompliance in this case was not based on any implied obligation for which Petitioner had no notice. Rather, it arose from Petitioner's failure to comply with *its own TB infection control policy*—which is specifically required under section 483.65. The regulations in Part 483 are clear that noncompliance regarding infection control could result in the imposition of sanctions. Petitioner's ancillary argument questioned “where in the regulation (or State law, or CDC Guidance), could [Petitioner's] staff and Medical Director find . . . the parameters [as to] when and why to shift specified responsibility *from* the public health agency *to* someone else (including themselves)?” P. Post-Hrg. Rep. Br. at 35-36 (emphasis in original). This argument is similarly flawed in that it erroneously articulates Petitioner's responsibilities regarding infection control under Federal law.

On appeal to the Board, Petitioner reasserts these arguments in describing the various ways the ALJ erred:

- ALJ did *not* address the context for *applying* the Center's TB Policy, starting with the undisputed fact that for more than two centuries, TB control in the United States has been, and is, primarily a local public health agency responsibility.
- ALJ determined there was no need to harmonize Petitioner's TB policy with State law or the CDC's guidance.
- ALJ inexplicably held that notwithstanding the clear provisions of State law and CDC guidance, it was Petitioner, and, specifically, its Medical Director and Infection Control Nurse, who failed to complete duties such as initiation

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of prophylaxis that *State law specifically assigned to the county*.

- ALJ never directly addressed the binding effect of these State laws and guidelines on Petitioner, or whether section 483.65 incorporates them as federal requirements.
- Maryland law, the CDC's TB guidance, and Petitioner's own TB Policy, all specifically assign responsibility for certain aspects of TB control, including the very tasks at issue here, to the local public health authority, in this case, the county.

RR at 2-4; P. Rep. Br. at 7.

There is nothing arbitrary or capricious about the ALJ's determination of the source of Petitioner's responsibility as a SNF participating in Medicare. The regulation establishes the requirement for a SNF to have an infection control policy under which it investigates, controls, and prevents infections in the facility; decides what procedures should be applied to an individual resident; and maintains a record of incidents and corrective actions related to infections. *See* 42 C.F.R. § 483.65(a)(1)-(3). The overarching premise of Petitioner's position is that section 483.65 says "nothing at all about TB"; CMS's SOM indicates SNFs "should follow specific State law and [CDC] guidance regarding the nuts and bolts of infection control for specific diseases"; and Maryland law and CDC Guidelines all specifically assign responsibility for certain aspects of TB control to the *local public health authority*, including the tasks which the noncompliance is based on. RR at 1-2, 7. Accordingly, Petitioner asserts

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that its determination to “*defer to the county*” was entirely consistent with the policy itself, State law, and CDC Guidance. P. Rep. Br. at 7 (emphasis added).

We find this argument neither persuasive nor supported by any evidence in the record. We reject Petitioner’s argument that the regulation does not apply to TB, as the version in effect at the time of the survey does not mention any disease by name, and more pertinently, Petitioner does not dispute that TB is an infectious disease. “[T]he federal requirements are based on an ‘outcome-oriented’ approach, in which the regulations establish outcomes facilities must achieve, but provide each facility with flexibility to select methods to achieve them that are appropriate to its own circumstances and needs.” *Azalea Court*, DAB No. 2352, at 9 (2010) (citing *Virginia Highlands Health Rehabilitation Center*, DAB No. 2339, at 5 (2010), citing *Lake Mary Healthcare*, DAB No. 2081, at 17 (2007)), *aff’d*, 482 F. App’x 460 (11th Cir. 2012). “[A] facility’s failure to take measures that are reasonably necessary, under the circumstances, to achieve an outcome required by the regulation” may establish “noncompliance, even though the regulation does not specify the particular measures that the facility must or may take to achieve these outcomes.” *Azalea Court* at 9. Moreover, Petitioner had a specific infection control plan for TB. It is the implementation, or lack thereof, of that plan that forms the basis for the non-compliance determination.

Petitioner’s assertion that the CDC and Maryland Guidelines, and COMAR specifically assign the initiation of prophylaxis to the county is not supported by the evidence. Petitioner argues that both the Maryland TB Guideline (CMS Ex. 39) and CDC guidance

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(P. Ex. 4, at 2; *see also* CMS Ex. 53, at 25) provide that the local health department is responsible for ensuring that all persons who are suspected of having TB are identified and evaluated promptly, that an appropriate course of treatment is prescribed and completed successfully, and regardless of where a person receives medical care, the public health agency is primarily responsible for ensuring the quality and completeness of all TB-related services. RR at 12-13.

Petitioner's argument is misplaced. The Maryland Guideline Petitioner relies on specifically refers to individuals with "*suspected*" TB or those confirmed to have active TB, not LTBI (emphasis added), and it requires the local health department to ensure that certain actions be taken, not requiring they be done only by the local health department. *See* CMS Ex. 39, at 10. The CDC guidance states "[c]ertain considerations for control of TB in hospitals apply also to extended care facilities, including 1) maintaining a high index of suspicion for the disease; 2) promptly detecting cases and diagnosing disease; 3) isolating infectious persons and initiating standard therapy" *See* CMS Ex. 53, at 60. Finally, Petitioner relies on CDC guidance stating that among the responsibilities of the local health department is to "medically evaluate *and treat*" and "*plan for treatment* and followup of contacts." RR at 13 (citing P. Ex. 4, at 6-7, 10); *see also* CMS Ex. 40, at 45. However, the first quoted phrase is incomplete. The cited language states, in full, that "[h]ealth departments are responsible for *ensuring* that TB contacts are medically evaluated and treated." *See* P. Ex. 4, at 6 (emphasis added). As previously stated, this does not require that the local health department itself perform the evaluation and

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treatment, but it must confirm or make sure that it is done. Moreover, none of this guidance absolves nursing homes of their responsibilities under 42 C.F.R. § 483.65 or makes local health departments exclusively responsible for preventing the development and transmission of TB in nursing homes.

Similarly, the “plan for treatment and follow-up of contacts” is again only a portion of the complete reference contained in the document. *Id.* at 10. The quoted language is found in the “Recommendations for Contact Investigations and for Outbreak Prevention and Response” section, and the topic of the cited provision is “TB-control programs should develop outbreak response plans for their jurisdictions.” *Id.* Another Guideline in the record addresses “Recommendations for TB Control in Health-Care Facilities and Other High-Risk Settings.” *See* P. Ex. 4, at 11-12; CMS Ex. 53, at 69-70. It states that residents admitted to long-term care facilities with TB infection should be offered treatment if indicated. *Id.* Simply put, no Guideline or guidance puts the sole responsibility for treatment and infection control on the local health department. Finally, as CMS points out, the Maryland Guidelines state either the local health department or a private provider may be responsible for prescribing an appropriate treatment regimen and ensuring it is adhered to and completed. *See* CMS Ex. 39, at 10. The treatment regimen, with listed medication, dosage, and duration, is also contained in this document. *See id.* at 20-21. The COMAR language only requires that the county health department recommend appropriate treatment for LTBI. *See* COMAR § 10.06.01.21(B)(2).

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The ALJ addressed these arguments, and held:

Petitioner provides no reasoned and supported argument that it should be relieved of the responsibilities to its residents it undertook when enrolling in Medicare. While the county had a duty under [COMAR] to recommend treatment for those residents with [LTBI], Petitioner should have been concerned with ensuring that none of the residents converted to active TB, exposing all staff and residents to TB and the need for treatment for [LTBI] or, much worse, active TB and possible death.

* * * *

The Maryland guidelines specify that either isoniazid (INH) or rifampin is used for treatment of latent TB infection for six to nine months depending on the treatment regime. Therefore, even absent a specific recommendation, Petitioner could have anticipated that the recommendation would be one antibiotic or the other. Further, Petitioner could have provided the Maryland guidelines to the residents' treating physicians and then relied upon those physicians to issue appropriate orders for treatment. The Maryland guidelines specify that a private provider undertaking to treat one with TB is undertaking a public health function that includes prescribing an appropriate treatment regime and ensuring adherence to that regime until treatment is completed. Therefore, the Maryland guidelines specifically provide for a private provider ordering

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and treating one with TB and impose the obligation to ensure that treatment is completed.

* * * *

Petitioner asserts there is nothing in the regulations that shifts responsibility for handling a TB outbreak to [its] staff or medical director. Petitioner overlooks, however, its responsibilities under 42 C.F.R. § 483.25 to ensure its residents receive necessary care and services . . . [and] its own policy, which places upon [its] staff the responsibility to ensure medical evaluations for treatment are accomplished for those with [LTBI]. . . . The fact the county was not fulfilling its duty is no excuse for Petitioner's failure to fulfill its duty to its residents. In this case, Petitioner's own policy required [it] to ensure that medical evaluation for treatment of [LTBI] was done, and [it] failed to follow that policy, which is the basis for the deficiency citation.

ALJ Decision at 47-49 (internal citations omitted).²⁴

²⁴ The ALJ noted that the quality-of-care requirements of 42 C.F.R. § 483.25 were revised effective November 28, 2016, but the regulation number and the requirement to ensure that residents received necessary care and services were unchanged. ALJ Decision at 46 n.26 (citing 81 Fed. Reg. 68,688, 68,745). Later in the decision, the ALJ further indicated that "I recognize that CMS did not charge Petitioner for either failure to deliver necessary care and service or neglect. I consider only the practical effect of Petitioner's action." *See id.* at 60 n.31. Petitioner has not challenged the ALJ's reference to, or analysis of, 42 C.F.R. § 483.25 on appeal. While CMS did not cite any violation of section 483.25, there is no dispute that section 483.65

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In order to participate in Medicare, a SNF must meet that program's requirements for participation. Act § 1819(a)(3), (b)-(d); 42 C.F.R. § 483.1. The chief purpose of those requirements, and of the laws adopted to enforce them, is to promote and protect the health, safety, and rights of a SNF's Medicare residents. *See Avon* at 2 (citing Act § 1819(f)(1)); *see also Northeastern Ohio Alzheimer's Research Ctr.*, DAB No. 1935, at 8 (2004) (discussing the "regulatory goal" of the enforcement scheme for Medicare-participating SNFs). The ALJ correctly held that Petitioner had an independent obligation under the Federal regulations to establish and maintain an ICP to provide a safe and

imposes on a SNF the responsibility to identify and adopt as policy—and then meet—adequate infection control standards. The Board has found that 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.” *See Golden Living Ctr.-Superior*, DAB No. 2768, at 23 (2017). The Board further stated, “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*.” *Id.* (emphasis added) (citing *Omni Manor Nursing Home*, DAB No. 1920, at 23 (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). We focus our review on the cited deficiency of section 483.65, but do so with the understanding that infection control is a distinct quality of care obligation which Petitioner is obligated to provide to “protect the health and safety of its residents who are the intended beneficiaries of the [Medicare] program”. *See Sanctuary at Whispering Meadows*, DAB No. 1925, at 9 (2004), *aff'd*, 151 F. App'x 386 (6th Cir. Oct. 7, 2005).

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sanitary environment, and help prevent the development and transmission of TB, and to timely and fully implement protocols called for by its infection control program after the TB exposures in 2015: (1) medical evaluation for prophylactic treatment of residents with LTBI; and (2) administering appropriate prophylactic treatment to residents with LTBI. *See* 42 C.F.R. § 483.65; CMS Ex. 30, at 8; CMS Ex. 53, at 17 (CDC recommended strategies for controlling TB in the United States include identification of people with LTBI that are at risk for progression to active TB and treatment with an effective drug regimen); *see also* P Ex. 6, at 2, 6-7 (Petitioner’s infection control policy required it to follow its own post-exposure policy to “proceed with evaluation for chemoprophylaxis” for residents with LTBI and determine treatment needed for patients; the purpose of those protocols is to help prevent the development of active TB for those determined to have LTBI, which in turn serves to minimize or control the spread of infectious disease having the potential to cause serious or life-threatening illness to all residents). Nothing in that process was dependent on involvement of the county.

The Board has held that the facility’s policy may also show the “standard of care the facility expected its staff to provide”). *Logan Healthcare Leasing, LLC d/b/a Logan Care and Rehabilitation*, DAB No. 3036, at 14 (2021) (citing *Oxford Manor*, DAB No. 2167, at 5 (2008)). Petitioner’s failure to implement the protocols (absent evidence that they were unnecessary or violated professional standards of care) constitutes noncompliance with section 483.65. The Board has long held that the regulation requires a SNF not only establish, but “maintain”—implement—the policies

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and procedures of its infection control program. *See Golden Living Ctr.-Superior* at 7; *see also 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”), *appeal dismissed*, 14-60388 (5th Cir. 2014); *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*, DAB No. 2005, at 60 (2005) (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”).

As such, there was a regulatory obligation for Petitioner to implement its infection control policy, not an ad hoc requirement created by the ALJ. Having determined a regulatory obligation, we turn now to whether the ALJ erred in determining that CMS met its burden to establish noncompliance, and Petitioner failed to show substantial compliance by a preponderance of the evidence.

2. Substantial evidence in the record supports the ALJ’s finding that Petitioner was not in substantial compliance with 42 C.F.R. § 483.65.

The noncompliance determination included the failure to implement infection control protocols specifically designed and intended to contain an outbreak of a contagious disease. In 2015, at least 19 residents, including RI, had positive TB tests and negative CXRs, indicating those residents had LTBI. The un-

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disputed standard of care according to the CDC, Maryland Guidelines, and the expert witnesses, is treatment of LTBI to avoid progression to active TB, except when treatment is contraindicated or refused. See ALJ Decision at 41, 57 (citing for CDC: CMS Exs. 41, at 55; 53, at 17, 60, 70; P. Ex. 4, at 7; for Maryland: CMS Exs. 30, at 8; 39, at 12-14, 19, 20-21, 28-30, 59; testimony of both expert witnesses: CMS Ex. 49, at 131; P. Ex. 31, at 13-15; Tr. 713-14). Petitioner conceded that any resident with a positive skin test and negative CXR (LTBI) should be treated. P. Post-Hrg. Br. at 3; see also Tr. at 864 (Genesis Vice Pres. of Medical Affairs), 1032 (ICRN), 1094 (DON). Petitioner's own policy states that all patients exposed to TB will be screened based on guidelines from the state/local agency to reduce the risk for TB among patients and to provide appropriate management post exposure, to include following the post exposure procedure requiring "evaluation for chemoprophylaxis" for patients with positive TB tests and negative CXRs to "determine treatment needed for patients." See P. Ex. 6, at 1, ¶ 2.2.1, ¶ 3.5.

a. Petitioner did not obtain medical evaluation for prophylactic LTBI treatment as required by its infection control policy.

Petitioner conceded that no diagnosis of LTBI was noted in any of the resident's clinical records, and there were no care plans for dealing with LTBI for the 19 residents because no physician from the county or the facility rendered such a diagnosis. ALJ Decision at 38 (citing Tr. at 143-44). The undisputed evidence is that planning for treatment in this case was done from the very first meeting in May of 2015. The county told Petitioner's leadership and the ICRN that

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Petitioner would be responsible for treating its residents. Petitioner understood from the outset that it was responsible for the administration of LTBI prophylactic treatment. Tr. at 478, 575, 996.

The ICRN testified that to her recollection, prior to 2015 there had not been a TB case at Petitioner's facility in 25 years, and as a result, the facility requested the county provide treatment recommendations.²⁵ Tr. at 975-76. The ICRN stated, "We're just not familiar with what a resident would be put on specifically for this type of exposure that we were dealing with . . . we were asking for recommendations as far as the type of medication, duration. I was not familiar with what would be the standard." *Id.* at 999-1000. The ICRN further testified that prior to contacting the county for any reason, she was required to consult with the Genesis Sr. VP of Medical Affairs. *Id.* at 977-78. The ICRN's recollection of any discussion at the initial meeting with the county regarding medication was limited to responding to a question as to whether the county would provide the medication, indicating no, the facility would provide the medication, but no specifics as to what medications would be involved, or the timing of prophylaxis, or categories of who would receive it. *Id.* at 996, 999.

²⁵ We note that because the Maryland Guidelines and COMAR required the county to provide recommended treatment for LTBI, Petitioner would not have had to request the county do so. The record established that neither the county witnesses who testified, nor the surveyor, were aware of that requirement. We infer that Petitioner became aware of this requirement after the survey and IDR. *See* Tr. at 192, 492; 511, 575-576, 999-1000; *cf.* Tr. at 8. This is not dispositive to our review but provides useful context to the seemingly inconsistent evidence prior to, and after, the request for ALJ review.

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Petitioner's Med. Dirs. (Dr. P (2015) and Dr. A (2016)) did not testify at the hearing, but both the county Nurse Administrator and county Case Manager testified that in the early stages of the contact investigation, when the notification letters were being drafted (which Dr. P was going to sign along with the County Health Officer), there was a conference call with Dr. P and the subject of follow-on treatment was addressed. *See* Tr. at 526, 583. According to the county Nurse Administrator, Dr. P clarified that he was ok with Petitioner doing the follow-on treatment for the residents and asked what was usually recommended for prophylactic treatment, to which she replied, "[INH] and vitamin B6 for nine months" and "he seemed familiar with that by his response" of "Oh, yeah." *Id.* at 526-29. The county Case Manager testified that in a conversation involving prophylactic treatment being done by Petitioner, Dr. P replied, "Oh yeah, INH and B6, Yeah, I know." *Id.* at 583.

Petitioner's infection control policy's intended purpose was to reduce the risk for TB among patients and to provide appropriate management post exposure. P. Ex. 6, at 1. For patients with positive skin tests but negative CXRs, Petitioner was required to proceed with medical evaluation for chemoprophylaxis. *Id.* at 6-7.

While Petitioner's initial request to the county for recommended treatment was appropriate at the time it was made, that did not end Petitioner's responsibility under its own policy. Petitioner asserts that it applied or implemented the "tasks" of recommending and initiating treatment by "defer[ring]" to the county. P. Rep. Br. at 7. Therein lies the problem. Petitioner, not the county, had the responsibility to

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provide treatment *and management* of multiple residents identified as having been exposed to active TB, specifically to evaluate the residents for prophylactic treatment. Much was made about the absence of a diagnosis in the records, but whether the diagnosis was documented or not, Petitioner was awaiting treatment recommendations—which implies that the residents had a medical need for treatment, unless contraindicated. Petitioner’s reliance on the absence of a documented diagnosis argument is misleading, as the testimony of Petitioner’s witnesses indicated that diagnoses were only documented when medications (treatment) were ordered. In summary, Petitioner knew its own policy and procedure established a need to evaluate the infected residents for treatment, and that did not happen in 2015.

Counsel and the ALJ questioned Petitioner’s ICRN and DON as to when a “diagnosis” for LTBI or a positive TB skin test would be entered in a resident’s clinical record. The DON agreed that if a resident had a positive skin test and a negative CXR, that is diagnostic of LTBI, but would not be considered a “new diagnosis” because the resident “is not on any medication.” *Id.* at 1077-78. The ALJ stated, “Well, it would still be a diagnosis, even if you’re not treating it” (*id.* at 1078), to which the DON replied, “The doctors don’t (inaudible) a diagnosis on the patient’s chart. We are not also going to note it because there was nothing to document on that patient since there was no signs or symptoms of TB to monitor.” *Id.* The DON also testified that if a resident tests positive for TB exposure and has a negative chest x-ray, Petitioner’s staff simply monitors for symptoms of active disease. *See id.* at 1086-88. That approach to residents having

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LTBI is not consistent with Petitioner's infection control policy, requiring the facility to "proceed with evaluation for chemoprophylaxis." P. Ex. 6, at 6. Additionally, Petitioner's ICRN testified that no treatment from an outside physician would have been provided to a resident unless the attending agreed with it, and *independently* issued an order for said treatment. Tr. at 1058-61 (emphasis added).

The ALJ summarized the DON's testimony as "no, our facility does not document a diagnosis of [LTBI] . . . all nurses know they're supposed to monitor for conversion to active TB" to which the DON said "yes"; and "so the fact that a patient may have [LTBI], you're not really treating them any differently, is that correct?" to which the DON replied "No, we don't treat them differently." *Id.* at 1079-81. The ALJ noted the DON's "suggestion" that only monitoring of a resident with LTBI is all that is required is clearly at odds with CDC guidelines. *Id.* The ALJ found this portion of the DON's testimony not credible, but indicated even if it was, it did not outweigh Petitioner's policy and procedure that required medical evaluation for treatment for a resident identified as having LTBI. *See* ALJ Decision at 42-43.

While we agree that the testimony is difficult to reconcile on its face, the DON's testimony was consistent with the absence of documented diagnoses of LTBI in the residents' records, and the ICRN's testimony that medication orders had to be initiated by an attending physician, which was not done until the fall of 2016 for all residents except R4. *Compare* Tr. at 1075-79 (DON) *with* Tr. at 1036-42 (ICRN).

Before the Board, Petitioner contends that nowhere does its policy say that an evaluation for prophylactic

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treatment must be—or even should be—performed or ordered by a resident’s primary care physician. P. Rep. Br. at 9. Again, Petitioner ignores the very language in its own TB infection control plan which explicitly states to follow its post-exposure procedure to *determine treatment needed for patients*. See P. Ex. 6, at 2. The infection control plan applies to Petitioner’s staff, not the county or any other outside medical provider. Moreover, that is consistent with the very same Maryland Guideline cited above which states that individuals with a positive skin test “should be examined by a *provider*,” not a health officer, “to rule-out [active] TB disease and be evaluated for treatment of [LTBI].” See CMS Ex. 39, at 19. Petitioner further contends CMS cannot dispute “that the timing of *when* nursing facilities can ‘treat’ residents is triggered by the receipt of valid orders.” P. Rep. Br. at 11. Again, while true, this statement evades the evidence that Petitioner’s practice required those valid orders be initiated by a facility physician. Additionally, Petitioner contends that the threshold issue is not “*whether* some twenty residents required evaluation for prophylaxis at some point . . . but *who* would do the evaluations and give the necessary prophylaxis orders.” *Id.* (emphasis in original). Petitioner argues that in requesting the county medical director evaluate and prescribe prophylaxis orders, they had “initiated” such evaluations and therefore had done what its policy required. *Id.* Finally, Petitioner asserts that it was not unreasonable for the ICRN to continue to wait on the county health department even after January 2016, because there was an agreement to delay treatment for LTBI until after the second round of testing was done. See RR at 15-16, 33-34.

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We do not find these arguments persuasive. The ALJ correctly noted that there was no evidence that any of the Petitioner's attending physicians, Medical Director, or the county health medical director were involved in the decision to delay treatment. *See* ALJ Decision at 35-36. The ALJ further noted that CMS's expert witness opined that while the decision to delay treatment was acceptable, the residents should have been diagnosed with LTBI not later than September 2015. *Id.* at n.17 (citing CMS Ex. 49, at 53-54). Petitioner ignores its independent obligation to manage and evaluate for prophylactic treatment multiple residents identified as having been exposed to active TB, to prevent conversion of even one resident to active TB. Furthermore, Petitioner only *requested* the county provide evaluation and recommended treatments, but never received any recommended treatment orders.

Petitioner further points out that the county exhibited no urgency about treatment at any time in 2015. RR at 16, 19. Whether the county expressed any urgency is inconsequential to the lack of action by Petitioner—who had the obligation to implement its infection control policy. The county inquired about whether the treatment had been started in November of 2015. The ICRN response of “nothing had been started” did not in any way indicate it could not start treatment because it had not received the recommended treatment orders, but only said it had a new medical director, “when is a good time to talk . . . We will need to coordinate process.” *See* P. Ex. 18, at 4-6. We disagree with Petitioner's assessment that the county “conceded the obvious” that one could interpret this email communication to mean Petitioner was still

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awaiting the treatment recommendations. *See* RR at 33 (citing Tr. at 617). Moreover, Petitioner's expert witness testified that even without recommendations from the county, Petitioner had the ultimate responsibility to ensure residents with LTBI received prophylactic treatment. *See* Tr. at 713.

In summary, we find that Petitioner never *obtained* the medical evaluations for appropriate LTBI treatment required by its infection control policy.

b. Petitioner did not appropriately manage residents found to have LTBI in accordance with its own TB Infection Control Policy.

The purpose of Petitioner's own policy was to reduce the risk for TB among patients and provide appropriate management post-exposure. *See* P. Ex. 6, at 1. Petitioner's policy and procedures required assessment and management of any resident who had a positive TB skin test in the 2015 post-exposure testing. Federal regulations required an infection control plan to investigate, control, and prevent infections in the facility. *See* 42 C.F.R. § 483.65(a)(1). Petitioner's own policy further required that if a TB exposure occurs in the facility, Petitioner will conduct an investigation "per state guidelines" and screen exposed residents "based on guidelines from the state/local agency." P. Ex. 6, at 1. Maryland regulations require a facility to conduct annual symptom review and assess and manage a resident with a history of previous positive TB skin test, previous history of active TB, or positive skin test conversion in accordance with CDC Guidelines. *See* COMAR § 10.07.02.21-2(B)(1), (4), (5).

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As noted above, counsel for both parties and the ALJ spent a good deal of time asking questions regarding when a diagnosis would be entered, as well as when a “change of condition” would be documented for a resident with LTBI, when a care plan would be updated to monitor for signs and symptoms of active TB for a resident with LTBI, and whether a resident’s LTBI status would be included when residents received CXRs ordered for reasons unrelated to the TB screening process, or a resident was transferred to a hospital for any reason. *See* Tr. at 1032-53; 1073-88. The ALJ eventually narrowed the focus, stating “I’m not seeing any evidence that the interdisciplinary team [IDT] for each . . . of the 19 residents were actually informed of the latent TB diagnosis so that they could actually develop a care plan that included monitoring for signs and symptoms of active TB or conversion.” Tr. at 1036.

The ICRN testified the IDT members were aware of the positive skin tests but did not believe the care plans were updated until 2016; she would have been involved if they were and those actions did not require direction or guidance from the county. *Id.* at 1037-40.

The ICRN also testified that a finding of LTBI would trigger an update of the care plan for symptom surveillance, but a care plan would not be changed based solely on a positive skin test or positive QFT-G, but she did not know why. *See id.* at 1039, 1042-44. When asked by the ALJ if any additional monitoring would be required once CXR results were available, the ICRN testified “we would do the annual symptom surveillance” and then clarified that “the standard would be annually, and then when a resident presents with signs and symptoms, we would have to do that

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[monitor].” *Id.* at 1044. The ALJ followed up, asking, “So for nursing staff, and particularly since you had PRN²⁶ staff, to understand that they needed to be particularly attentive to signs and symptoms of conversion from latent to active [TB], would that not need to be somewhere in the care plan, arguably?” *Id.* at 1044. The witness responded, “yes, there should be a care plan.” *Id.* at 1045.

The ALJ explained the underlying basis for this line of questioning:

[Counsel], I’m fully aware that the facility was not cited for care planning deficiency, they weren’t cited for [Minimum Data Set] deficiency. I fully understand, and I’m not going to add any citations to the deficiencies. Don’t worry. That’s not—that’s not generally what I do. So don’t worry about that.

But I think I need to get some honesty here that there were things that this facility could have and should have done without waiting for the county to tell you what to do next.

There are certain things that are directed by the federal regulations, right? . . . So I just want to make sure that it’s clear that I understand what’s actually required of this facility when you get a positive diagnosis, note something.

Id. at 1045. Petitioner’s counsel did not disagree with the ALJ’s line of questioning, and indicated the DON

²⁶ PRN staff are healthcare professionals who work “as circumstances may require.” COMAR § 10.07.02.01.B(40) (2017).

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might be a better witness to address these issues. *Id.* at 1045-46. The DON testified that on admission, it was not Petitioner's practice to update a resident's care plan following a positive skin test and negative CXR, stating "[w]e continue to monitor the patient for any unusual signs and symptoms, and we report to the physician." *Id.* at 1075. The DON also stated that with a positive skin test and negative CXR, the care plan would be updated "if the patient was placed on medication like INH, Vitamin B", and "we monitor for any unusual signs and symptoms, and we report to the physician." *Id.* at 1076. The DON stated that care plans were updated for R4 in 2015, as well as for the residents who were put on prophylaxis in the fall of 2016. *Id.* at 1076-77.

CMS argued in its post-hearing brief, but did not cite to any reference document, that annual monitoring for signs and symptoms of active TB was inadequate for residents with LTBI, relying on the declaration and deposition testimony of its expert witness. *See* CMS Post-Hrg. Br. at 12-16; *see also* CMS Exs. 42 (Dr. M's declaration) ¶ 73; 49, at 87-88, 104-106 (Dr. M's deposition testimony that in the absence of treatment for LTBI, a strict monitoring schedule should be adhered to over the 2 years following exposure). The ALJ agreed "that annual monitoring is probably not adequate" but declined to find the monitoring to be deficient based on the absence of any citation that Petitioner's infection control policy was inadequate. *See* ALJ Decision at 43 n.24. Before the Board, CMS acknowledges that Maryland regulations only require annual symptom review. *See* CMS Br. at 5; *see also* COMAR § 10.07.02.21-2(B)(4).

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When the testimony is analyzed in context, it is clear that the actions, or inactions, of Petitioner all hinge on a determination, finding, or diagnosis of LTBI accompanied by an order for medication. Here, there had been no treatment ordered as Petitioner was awaiting recommended treatment from the county. Just as there is no evidence that any of Petitioner's physicians or nurse practitioners were asked to evaluate the residents for treatment, there is no evidence as to whether any of the attending physicians had determined or diagnosed any resident with LTBI, or whether they knew of the fact that Petitioner was awaiting recommended treatment from the county. Nevertheless, the evidence supports there was an expectation to treat absent contraindication, which supports that there was a determination or finding of LTBI that was not documented in the residents' records.

The ALJ opined on why the interpretation of Petitioner's policy by the DON and the ICRN was "inadequate to prevent or control outbreaks for TB." ALJ Decision at 25 n.16. The ALJ used the facts surrounding RI to illustrate this point:

[RI] was identified in May 2015 by a positive TB skin test and negative chest x-ray as having [LTBI]. [RI] was not treated for [LTBI] and was formally evaluated in May 2016, a year after initial identification, and determined not to have converted to active TB. One month later [RI] had signs and symptoms consistent with possible active TB that were not recognized as such, an oversight that may have been facilitated by

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the fact that [RI's] records did not clearly reflect the TB testing in 2015 and the [LTBI], either by a clear diagnosis or a care plan for the [LTBI].

Id.

We agree with the ALJ's determination that Petitioner's practices were inadequate to prevent or control infections, at least those involving LTBI. Most disconcerting is the fact that both the DON and the ICRN testified that even without an order for medication, those residents awaiting treatment recommendations would somehow need to be monitored for signs and symptoms of conversion to active TB. But without independent knowledge of a resident's TB status, or an overt entry in the resident's clinical record, the evidence provides no basis for how any staff member would know to be alerted to signs and symptoms of TB in any resident, let alone the 19 who were identified with LTBI in 2015. The ICRN testified that she did not know if staff "focused" on a given resident's immunization status, where the positive skin test would have been documented. ALJ Decision at 26. There is also no evidence of what, if anything, staff were instructed to do regarding monitoring these residents while awaiting suggested treatment regimens. Petitioner's own infection control policy required appropriate post-exposure management, including monitoring those with LTBI for signs and symptoms of TB to prevent the development and spread of active TB pursuant to the federal statute and regulations.

The ALJ highlighted the fact that only partial records of seven residents with LTBI were in the record. ALJ Decision at 43 n.24. Petitioner's post-exposure policy required a medical evaluation for patients with

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a positive skin test but negative CXR. *See* P. Ex. 6, at 6-7. Eighteen residents identified with positive skin tests in early 2015 fell into that category. Regarding RI, the ALJ found the nursing notes recorded RI's signs and symptoms in June and August of 2016 that could be consistent with active TB, but there is no mention or annotation of any concern by any staff member, or the attending physician, that these symptoms were recognized as related to TB and could indicate conversion to active TB. ALJ Decision at 43 n.24. The ALJ found the staff's failure was "more symptomatic of a lack of competency and inadequate training than a failure to implement Petitioner's infection control policy." *Id.* Whether staff's failure was indicative of lack of competence or lack of cognizance, the conclusion is the same—the residents identified with LTBI were not properly managed in accordance with the facility's own policy to prevent the development and spread of active TB, which constitutes a failure to implement its infection control policy.

Ultimately, Petitioner's decision not to indicate the TB status in its residents' records detracts from its assertion that it did everything it should have done. Not everyone with a cough necessarily needs to be characterized as possibly having TB. But someone with LTBI, who presents with a cough, and coughs up bright red blood, presents a very different situation. Pursuant to its infection control policy, Petitioner was required to reduce the risk for TB among patients and to provide appropriate management post exposure to reduce the risk of residents with LTBI from converting to active TB, and that involved more than simply the administration of medication if prescribed. The

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purpose of testing is to identify the presence of TB infection. It does no good to test if the results are not known to staff and providers responsible for providing appropriate care to those residents, which includes monitoring symptoms.

There is no question that the county did not provide assistance to Petitioner once the 2015 contact investigation was completed for all but a handful of residents requiring QFT-G blood draws. Nevertheless, Petitioner had an independent duty to comply with its own infection control policy, mandated by participation in Medicare. Petitioner had the obligation to appropriately manage the residents with LTBI starting in 2015. Petitioner's decision to abdicate its responsibilities to its residents and defer to the county was unacceptable. Petitioner had the obligation to do more than "what the county told them to do" and it failed to comply with those obligations. Petitioner's policy required it to reduce the risk for TB among patients, which clearly includes residents with LTBI at risk for converting to active TB. To control LTBI, prophylactic treatment is recommended, and as discussed further below, was in fact being administered to R4 by Petitioner's staff, with no involvement by the county health department. Petitioner did not establish that it had fulfilled the requirements of its own infection control policy to manage residents with LTBI by a preponderance of the evidence.

c. Petitioner did not provide prophylactic LTBI treatment until September of 2016 to any resident except R4.

Petitioner does not dispute that active TB is a contagious and life-threatening disease, and individuals

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with LTBI should be treated. Most importantly, Petitioner does not dispute that only one resident, R4, received prophylaxis LTBI treatment in 2015, and that treatment was ordered by R4's attending physician, and administered by staff at Petitioner's facility.

Even if Petitioner had received treatment *recommendations* from the county in 2015 for the residents identified with LTBI, Petitioner's ICRN clearly stated that no treatment from an outside source would have been provided to a resident unless their attending physician agreed with it, and *independently* issued an order for that treatment. *See* Tr. at 1058-61 (emphasis added). This process was illustrated by the events surrounding the determination to provide LTBI prophylaxis to R4 in October of 2015. A physician involved in R4's evaluation for a kidney transplant performed a TB skin test that came back positive and prescribed INH and Vitamin B6. However, while the ICRN provided that information to the county, Petitioner did not rely on any decision by the county prior to initiating the treatment. Instead, the prescribed treatment was reviewed, approved, and independently ordered by the attending physician. Only then did Petitioner's staff provide the INH and vitamin B6 treatment; no one from the county was involved in the treatment decision process. *Id.*; *see also* P. Ex. 20, at 2.

The example shows that it was not the county's failure to provide a treatment recommendation that prevented the additional residents from receiving prophylactic treatment, but the facility's failure to fulfill its responsibility under its infection control policy to evaluate the residents having LTBI for treatment. Accordingly, we affirm the ALJ's determination that

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Petitioner was not in substantial compliance with section 483.65.

B. CMS's immediate jeopardy determination, including the duration, was not clearly erroneous.

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. The CMS determination as to the level of noncompliance, including the finding of immediate jeopardy, “must be upheld unless it is clearly erroneous.” 42 C.F.R. § 498.60(c)(2). The Board has held 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.’” *Consulate Healthcare of Jacksonville*, DAB No. 3119, at 12 (2023) (citing *Mississippi Care Ctr. of Greenville*, DAB No. 2450, at 15 (2012), *aff’d*, 517 F. App’x 209 (5th Cir. 2013) (per curiam); see also *Brian Ctr. Health & Rehab./Goldsboro*, DAB No. 2336, at 8-9 (2010)).

The duration of the period of immediate jeopardy is also subject to the clearly erroneous standard. See *Vibra Hospital of Charleston-TCU*, DAB No. 3094, at 23 (2023) (citing *Universal Health Care* at 16; *Brian Ctr. Health and Rehab./Goldsboro* at 7-8; *Owensboro Place & Rehab. Ctr.*, DAB No. 2397, at 12-13 (2011)).

Petitioner challenges the ALJ’s upholding of CMS’s declaration of immediate jeopardy, asserting that “CMS speculates that perhaps [RI] was developing active TB in December 2015, or June 2016, and that her

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physician (and two radiologists) misdiagnosed her (ostensibly because they were flying blind because [Petitioner] did not document her LTBI in her nursing facility chart a certain way”); and because there was no actual noncompliance, the imposition of a sanction based on RI’s conversion to active TB due to Petitioner’s failure to provide timely prophylaxis to RI, is based on “fatal evidentiary (and legal) flaws.” RR at 36-38; P. Rep. Br. at 15-17 (emphasis omitted).

As discussed above, noncompliance was established. Furthermore, the ALJ found that based on the “undisputed risks for serious harm or death secondary to a conversion to infectious TB posed by even one resident in a long-term care environment, I would have no trouble concluding immediate jeopardy existed beginning no later than August 2015.” ALJ Decision at 57. The ALJ further concluded that RI “suffered actual harm” because of the failure to receive treatment for LTBI in 2015 and LTBI “converted to active TB” in 2016. *Id.* at 56. Moreover, in June of 2017, the “genotype” of RI’s TB was determined to be the same as staff member #1’s TB. *See* CMS Ex. 47. For the same reasons discussed above, Petitioner’s failure to follow its own policy and procedures to treat residents identified as having LTBI was directly related to RI’s disease progression from LTBI to active TB. There is nothing in the partial clinical record for RI that shows she had a history of TB exposure prior to 2015. *See* CMS Ex. 5, at 5 (RI’s annual symptom surveillance dated May 09, 2015 showing test results as NA, and evaluation of results indicating annual monitoring only); 2, 29-30, 36 (showing positive skin test on May 26, 2015, order for CXR to rule out TB, negative CXR results); *compare* P. Ex. 11, at 3 (showing RI’s name

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with no annotation of prior history (hx)) *with id.* at 4 (showing another resident with annotation of “Hx+”). There is no ambiguity or conjecture as to the source of RI’s exposure in 2015 and later disease progression.

Petitioner’s position is that “CMS simply assumes that [RI’s] disease must have progressed because of some (unexplained) breakdown in [Petitioner’s] implementation of its infection control or TB policies.” P. Rep. Br. at 16 (emphasis omitted). Petitioner further asserts that “even where the record supports a finding of some noncompliance . . . the record *also* must contain an *evidentiary* basis from which the ALJ or Board can infer that death or serious harm to one or more residents actually had been caused by, or was the ‘probable’ or ‘reasonably to be expected’ result of, the alleged noncompliance, and not just—to use CMS’s *own words*—‘possible,’ ‘potential,’ or ‘mere risk.’” *Id.* at 16-17 (citing *Oak Ridge Center*, DAB No. 2913 (2018) and *Golden Living Center-Trussville*, DAB No. 2937 (2019)).

We find these arguments unpersuasive and contradicted by the record evidence. Again, Petitioner ignores the requirement to comply with *its* regulatory responsibility to implement *its* TB infection control policy with the stated purpose to reduce the risk for TB among patients and to provide appropriate management post exposure. To the extent that Petitioner suggests that it could not provide treatment to the residents identified as having LTBI unless and until the county prescribed treatment, that position is both factually and legally incorrect. Furthermore, as discussed above, any treatment provided to a resident had to be ordered by the attending physician/nurse

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practitioner—even if another physician outside the facility had prescribed treatment. Many of the CXR orders signed by the facility physicians/nurse practitioners did indicate “TB test reaction” as the reason for the order, and most of those orders show the results were telephonically relayed to a named facility physician/nurse practitioner. *See* P. Exs. 9, 13. There is no evidence, documentary or testimonial, to establish whether the attending physicians or nurse practitioners for any of the residents identified as having LTBI were informed of the policy’s requirement to evaluate for prophylaxis when those CXRs ruled out active TB. Petitioner conceded that no diagnosis of LTBI was noted in any of the resident’s clinical records because no physician from the county or the facility rendered such a diagnosis. ALJ Decision at 38 (citing Tr. at 143-44). But there is no explanation as to why such a diagnosis was not made when treatment recommendations were pending.

The ICRN testified that RI had a history of emphysema and chronic obstructive pulmonary disease (COPD), along with other diagnoses, before May 2015. ALJ Decision at 26; *see also* Tr. at 1027. The ICRN also testified that RI had a positive skin test and negative CXR during the first round of testing in May 2015, but was not exhibiting any signs or symptoms of TB. ALJ Decision at 26; *see also* Tr. at 1026. The ALJ interpreted this evidence to indicate RI had LTBI, but that “is not reflected by the few documents from [RI’s] clinical record in evidence” and the ICRN was “not aware whether RI was considered to have a change in condition in 2015 when testing showed LTBI” and agreed that a review of nursing notes in 2016 (P. Ex. 10, at 1-4) did “not indicate that [RI] had [LTBI].” ALJ

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Decision at 26. We have previously discussed the ICRN's testimony that staff may not have focused on the resident's immunization status where the positive skin test would have been documented; that a determination that a resident had LTBI would trigger an update to a resident's care plan for symptom surveillance, but did not believe the IDT updated any resident's care plan based on the fact that testing showed a resident had latent TB; and that changes to a resident's care plan would "involve no direction or guidance from the county. *See infra*, citing Tr. at 1032-39. The ICRN's testimony also included that she did not believe that [LTBI] had been added to [RI's] or any resident's "face sheet," a document which follows a resident when transferred to a hospital. *See* Tr. at 1035. While there was no testimony as to whether or not the record contained a face sheet for any resident, the first page in RI's clinical record shows a date and time of "Dec. 3, 2015 15:41:57 ET" and LTBI is not shown as a diagnosis, and the listed diagnoses were entered at admission seven months earlier. *See* CMS Ex. 5, at 1.

The record clearly establishes that RI's attending physician ordered the initial CXR to rule out active TB and was notified of the negative result. The same attending physician also ordered the CXR in June of 2016, diagnosed the resident with bronchitis, and then in early August 2016, when RI was coughing up blood, ordered RI to be transferred to the hospital. *Id.* at 6-8, 47, 50, 61. The evidence regarding the transfer is disconcerting in that the date of transfer shows "I 0/27/2015" but shows "report called in" and "date sent" as August 8, 2016; contains "Resident observed with bright red moderate bleeding from her mouth" but the

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“Reason for transfer” is listed as “Other—GI bleeding” and there is no mention of TB status or possible conversion to active TB. *See* CMS Ex. 5, at 6-7. The surveyor interviewed RI’s attending physician and testified that the doctor “did not recall” if RI’s TB status was documented in 2015. While that response is corroborated by the testimonial evidence and the minimal clinical record evidence provided, it provides no meaningful evidence of whether the attending physician was aware of RI’s TB status, and how, if at all, the attending physician factored that information into the medical symptoms RI experienced throughout 2015 and 2016 prior to being diagnosed with active TB. We find the totality of information associated with the transfer to be compelling evidence that TB was not considered by the facility at the time of transfer.

Petitioner’s argument that the county failed to comply with its requirement to make specific prophylaxis recommendations for residents who had tested positive for exposure does not “justify” or absolve its own failure to implement its own TB infection control policy and procedures. Petitioner provided no evidence that the attending physicians or nurse practitioners were asked to evaluate the residents determined to have LTBI for prophylactic treatment or asked to order LTBI treatment; and if not, why not. We agree with the ALJ’s assessment that the absence of documentation means that there is little or no documentation that Petitioner’s staff actually did what was required by its policy and procedures, i.e., medical evaluation by physicians to determine the best plan of care including treatment for LTBI, if not contraindicated,

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and monitoring. Given these circumstances, Petitioner's failure to implement post-exposure TB procedures fully or promptly, namely medical evaluation, prophylactic treatment and appropriate management of the infected residents, was likely to cause serious harm to residents. In addition to the harm directly to those residents who could convert to active TB, they would now be contagious and pose a risk to expose the remaining residents to TB. The ALJ noted the CDC Guidelines found treatment of LTBI can reduce the risk for death due to conversion to active TB, and correctly concluded for all residents with LTBI there was a risk for actual harm due to the risk for death associated with conversion to active TB, as demonstrated by RI. ALJ Decision at 41, 43. Thus, the ALJ did not err in concluding that CMS's immediate jeopardy determination was not clearly erroneous.

The county was not involved in the prophylactic treatment ordered and provided to R4 by Petitioner's staff. The treatment regimen prescribed for R4 was exactly the same as what the county health department prescribed in 2016—INH 300 mg daily together with Vitamin B6 50 mg daily—and corresponded to the regimen and dosage provided in CDC guidance. *See* P. Ex. 14; P. Ex. 26; CMS Ex. 30, at 18; CMS Ex. 39, at 20, 22. CMS's determinations of noncompliance and immediate jeopardy and the ALJ's upholding of those determinations are based on failures of Petitioner to implement its TB infection control policy. In short, Petitioner made no meaningful attempt to carry its heavy burden to show clear error by CMS.

Accordingly, we affirm the ALJ's finding that Petitioner failed to establish that CMS's declaration of immediate jeopardy was clearly erroneous.

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Petitioner also challenges 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 June 14 through October 5, 2016. Petitioner argues that "it is not at all clear what, if anything, these dates have to do with the noncompliance CMS alleged or the ALJ actually sustained." RR at 36. We reject Petitioner's assertions.

The SOD did not contain a start date for the immediate jeopardy, which the ALJ noted as "odd" at the hearing, but the CMS determination notice did. *See* Tr. at 59-60; *see also* CMS Ex. 20. At the hearing, CMS argued that the inception of immediate jeopardy of June 14, 2016, was a "typo" and should have been June 4, 2016. Tr. at 56-57. The ALJ stated that changing the start date of immediate jeopardy is not a matter of "correcting a typographical error," but is instead a substantive change in the enforcement remedy proposed by CMS that would increase the CMP by more than \$120,000. Tr. at 56-57, 62, 65-66; *see also* ALJ Decision at 58 n.30. The ALJ further held that CMS can only reopen and revise its initial determination within 12 months of the date on the notice of the initial determination, and here, counsel raised this issue more than 18 months after the date of the initial determination. Tr. at 66-67; ALJ Decision at 58 n.30 (citing 42 C.F.R. § 498.30). CMS articulated that the choice of the start date of non-compliance at the immediate jeopardy level was an exercise of "selective enforcement," asserting Petitioner could have been cited in September of 2015. *See* Tr. at 122-25.

The ALJ found that the evidence showed that RI was identified as having LTBI in 2015, was provided

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no treatment for LTBI, and as a result developed active TB no later than August 2016. ALJ Decision at 49. The ALJ also found that based on the “undisputed risks for serious harm or death secondary to a conversion to infectious TB posed by even one resident in a long-term care environment, I would have no trouble concluding immediate jeopardy existed beginning no later than August 2015.” *Id.* at 57. Nevertheless, the ALJ did not disturb CMS’s exercise of discretion and concluded the immediate jeopardy existed no later than June 14, 2016, and ended October 5, 2016. *Id.* at 58. The ALJ further found Petitioner had not shown that the duration was clearly erroneous. *Id.*

The Board has previously held that a facility’s non-compliance, or failure to meet a participation requirement, “is what constitutes the deficiency, not any particular event that was used as evidence of the deficiency” and “there is no requirement that the duration of a remedy coincide with particular events that form the evidence of lack of substantial compliance.” *Regency Gardens Nursing Ctr.*, DAB No. 1858, at 21 (2002) (citing 42 C.F.R. § 488.301). Furthermore, the Board has held that CMS is not “under any compulsion to explain why it decides not to impose remedies on days for which it might do so. From the provision that remedies may be imposed as early as the first day of noncompliance, it follows that CMS may choose to begin any remedy at a later date.” *Id.* at 10 (emphasis omitted); *see also Mountain View Manor*, DAB No. 1913, at 6 (2004) (upholding CMP beginning on May 25 because immediate jeopardy existed as of that date, despite unclear reasoning why that date was chosen). Still further, Petitioner made no showing that it abated the immediate jeopardy before October 5,

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2016. *See Owensboro Place & Rehab. Ctr.*, DAB No. 2397, at 12-13 (2011) (“[I]t is not incumbent on CMS to justify the [abatement] date, but, rather, on [the facility] to show an earlier date of abatement . . .”).

Accordingly, we find no error in the ALJ’s conclusion that CMS’s determination concerning the duration of immediate jeopardy (June 14, 2016 through October 5, 2016) was not clearly erroneous. *See* 42 C.F.R. § 498.60(c)(2) (“CMS’s determination as to the level of noncompliance of a SNF . . . must be upheld unless it is clearly erroneous.”); *Brian Ctr. Health and Rehab./Goldsboro*, at 7-8 (“A determination by CMS that a SNF’s ongoing compliance remains at the level of immediate jeopardy during a given period constitutes a determination about the ‘level of noncompliance’ and, therefore, is subject to the clearly erroneous standard of review under section 498.60(c)(2).”).

As Petitioner “does not contend that [the per day CMP amount] is unreasonable based on the relevant regulatory factors,” we “find no basis for disturbing the ALJ’s conclusion that the amount of the CMP was reasonable.” *See Lutheran Home at Trinity Oaks*, DAB No. 2111, at 22 (2007); *see also Glenoaks* at 27 (upholding CMP amount where petitioner did “not contend . . . on appeal . . . that any particular regulatory factor did not support the CMP amounts”).

C. We reject Petitioner’s arguments based upon Jarkesy.

Concerning *Jarkesy*, Petitioner argues the Supreme Court “held that where, as here, an agency imposes a CMP for regulatory noncompliance, such a CMP is equivalent to a common law remedy, and thus the Seventh Amendment requires that a jury, not an ALJ,

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must consider a challenge to that remedy in the first instance.” P.’s *Jarkesy* Mot. at 1. “Accordingly,” Petitioner asserts, “this appeal proceeding was void ab initio, and so the Board should,” among other things, “hold that under *Jarkesy* the ALJ did not have constitutional authority to conduct this review[.]” *Id.* at 3; *see also* P.’s *Jarkesy* Reply at 1 (“[T]his proceeding is void ab initio.”). Petitioner further contends that “if, as *Jarkesy* holds, the due process necessary in a CMP appeal is a jury trial, then CMS must meet that constitutional command and return the ‘escrowed’ [CMP] funds pending such review.” P.’s *Jarkesy* Mot. at 3.

CMS counters that “the Board consistently has held that ALJs do not have the authority to consider constitutional challenges. *Jarkesy* does not invalidate those prior decisions or their reasoning that this type of constitutional challenge may not be heard before an ALJ or the DAB.” CMS *Jarkesy* Opp. at 1. “Therefore, there is no authority to remand based on a purported Seventh Amendment infirmity in the long-standing process for review of CMS enforcement actions.” *Id.* at 2. CMS considers Petitioner’s refund request to be “premised on the same unreviewable Seventh Amendment claim” and therefore states that the Board “must deny this request.” *Id.*

We reject Petitioner’s arguments for remand and refund of the CMP based upon *Jarkesy*. That case arose from “an enforcement action” by the Securities and Exchange Commission (SEC) pursuant to the Securities Act of 1933, the Securities Exchange Act of 1934, the Investment Advisers Act of 1940, and the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010. *Jarkesy*, 603 U.S. 109, 115-16

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(2024). The SEC brought an enforcement action seeking CMPs from an investment advisor company and its individual manager for alleged securities fraud, and the SEC elected to proceed before an ALJ. *Id.* at 115, 117-118. The Supreme Court addressed the question “whether the Seventh Amendment permits the SEC to compel respondents to defend themselves before the agency rather than before a jury in federal court,” and concluded that “[t]he Seventh Amendment . . . applies and a jury is required.” *Id.* at 115, 120-21.

We reject Petitioner’s attempts to equate this case with *Jarkesy*. This case concerns an entirely separate statutory and regulatory regime administered by the U.S. Department of Health and Human Services, an issue that was not even before the Court, which held that the “SEC’s antifraud provisions replicate common law fraud, and it is well established that common law claims must be heard by a jury.” *Jarkesy*, 603 U.S. at 120. The Court did not hold that every agency’s attempt to impose and enforce CMPs necessarily is, like the SEC’s action, “a common law suit in all but name” that “must be adjudicated in Article III courts.” *Id.* at 136. On the contrary, the Court acknowledged the long-established “public rights exception,” under which “Congress may assign [a] matter for decision to an agency without a jury, consistent with the Seventh Amendment,” and extensively discussed the Court’s precedents applying that exception. *Id.* at 127-132. The Supreme Court did not decide the potential applicability of that exception to the Act and its implementing regulations concerning imposition and enforcement of CMPs for noncompliance with Medicare participation requirements.

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As CMS argues, “The Board has consistently held that ALJs may not declare a statute or regulation to be unconstitutional and refuse to apply or follow the statute or regulation on that basis.” *Fady Fayad, MD.*, DAB No. 2266, at 14 (2009), *aff’d*, 803 F. Supp. 2d 699 (E.D. Mich. 2011); *see also Borgess Med. Ctr.*, DAB No. 3106, at 42 (2023); *Russell L. Reitz, MD.*, DAB No. 2748, at 8 (2016). The Board is not authorized to invalidate or declare unconstitutional any part of the Act, or its complex implementing regulations and refuse to enforce it for any reason. Instead, the Board “must follow applicable statutes and regulations,” and we do so in this case. *See The Oaks*, DAB No. 3160, at 28 (2024); *Linda Silva, P.A.*, DAB No. 2966, at 12 (2019). We cannot anticipate how federal courts may apply the reasoning of *Jarkesy* in different circumstances, including in the context of the long-standing and complex statutory and regulatory regime governing imposition of CMPs upon SNFs, like Petitioner, that CMS deems noncompliant with the conditions of Medicare participation. Accordingly, we deny Petitioner’s motion.

Conclusion

We affirm the ALJ Decision upholding CMS’s determinations that Petitioner was not in substantial compliance with 42 C.F.R. § 483.65, from June 14 through October 5, 2016, at the immediate-jeopardy level. We also affirm the ALJ’s conclusion that the \$12,541 CMP imposed for each day during the immediate jeopardy period was reasonable. Finally, we deny Petitioner’s motion for relief based on *Jarkesy*.

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Michael Cunningham

Michael Cunningham

Susan S. Yim

Susan S. Yim²⁷

Karen E. Mayberry

Karen E. Mayberry

Presiding Board Member

²⁷ Former Board Member Susan S. Yim fully participated in all deliberations concerning this matter and, before her retirement, reached consensus with the Board on the final decision and reviewed and approved it.

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Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Sligo Creek Center
(CCN: 215327),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-17-458

Decision No. CR5745

Date: October 23, 2020

DECISION

Petitioner, Sligo Creek Center, was not in substantial compliance with program participation requirements from June 14 through December 11, 2016, due to violations of multiple participation requirements established by 42 C.F.R. pt. 483.¹ There is a basis for

¹ Citations are to the October 1, 2016 revision of the Code of Federal Regulations (C.F.R.), which were in effect at the time the survey was completed in this case, unless otherwise stated. In *Mark A. Kabat, D.O.*, DAB No. 2875 at 9-11 (2018), an appellate panel of the Departmental Appeals Board (Board), after reviewing prior Board decisions, expressed a preference for applying the regulations in effect at the time of agency action rather than at

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the time of the events that were the basis for the agency action, at least in provider and supplier revocation cases. In this case, the events that are the basis for the agency action occurred in 2015 and 2016, and the complaint investigation that is the basis for the agency action concluded on October 6, 2016. The surveyor cited a violation of 42 C.F.R. § 483.65, which was the infection control regulation in effect throughout 2015 and through the end of the survey on October 6, 2016. Centers for Medicare & Medicaid Services (CMS) Exhibit (Ex.) 1 at 5. The provisions of 42 C.F.R. § 483.65 were unchanged during the period of 2015 through completion of the survey. Therefore, the regulation with which Petitioner was bound to comply during the period at issue, 2015 through completion of the survey on October 6, 2016, were the same. However, effective November 28, 2016, the requirements related to infection control were moved to 42 C.F.R. § 483.80. 81 Fed. Reg. 68,688, 68,697 (Oct. 4, 2016). The initial determination by CMS was issued on January 31, 2017. CMS Ex. 20 at 1-5. Therefore, the revised regulation effective November 28, 2016, would arguably apply under the Board's rationale in *Kabat* and cases cited therein. The revision of the infection control regulation under 42 C.F.R. § 483.80 was significant. At hearing, I advised the parties that I would apply the version of 42 C.F.R. § 483.65 in effect October 1, 2016. The parties have not objected. Tr. 99-100. Due to the significant change in the infection control standard under 42 C.F.R. § 483.80, remand to CMS for revision of the Statement of Deficiencies (SOD) and a new initial determination was possible. However, it is also possible to compare the provision of 42 C.F.R. § 483.65 and 42 C.F.R. § 483.80, and conclude that the participation requirement allegedly violated is found in both regulations. The surveyor cited 42 C.F.R. § 483.65(a), (b), (c). CMS Ex. 1 at 5-6. Subsection (a) requires that a facility establish an infection control program to accomplish specific tasks. Subsection (b) requires that a facility prevent the spread of infection by accomplishing specific tasks. Subsection (c) has no application based on the allegations in the SOD. Pursuant to 42 C.F.R. § 483.80(a), a facility must establish an infection control program and specific elements for such a program are listed. Subsection (a) of 42 C.F.R. § 483.80 incorporates the provisions of 42 C.F.R. § 483.65(b) in substantial part. Therefore, it is possible to simply read a citation to 42

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the imposition of enforcement remedies. The following enforcement remedy is reasonable: a \$12,541 per-day civil money penalty (CMP) from June 14 through October 5, 2016, and a \$303 per-day CMP from October 6 through December 11, 2016, for a total CMP of \$1,449,975.

I. Background

Petitioner is located in Takoma Park, Maryland, and participates in Medicare as a skilled nursing facility (SNF) and the state Medicaid program as a nursing facility (NF). Joint Settlement Status Report, Joint Stipulations of Undisputed Facts (Jt. Stip.) ¶ 1, and Joint Statement of Issues Presented for Hearing. On September 27 and 28, and October 6, 2016, the Montgomery County, Maryland Department of Health and Human Services (state agency) completed a survey of Petitioner that was triggered by a complaint. The state agency found Petitioner was not in substantial compliance with program participation requirements. CMS Exs. 1, 19 at 1-34; Jt. Stip. ¶ 2. On December 12, 2016, the state agency conducted a revisit survey and concluded that Petitioner had returned to substantial compliance effective that day.² CMS Ex. 19 at 35-44; CMS Ex. 20 at 2. CMS notified Petitioner by letter dated January 31, 2017, that it was imposing the following enforcement remedy: a

C.F.R. § 483.65(a) and (b) as a citation to 42 C.F.R. § 483.80(a) without prejudice to either party, if that is deemed necessary.

² The parties incorrectly stipulated that the CMP in this case ran through December 12, 2016. Jt. Stip., 5. However, the fact the state agency determined that Petitioner returned to substantial compliance effective December 12, 2016 (CMS Ex. 19 at 35-44), ended the accrual of the CMP effective December 11, 2016 (CMS Ex. 20 at 2). 42 C.F.R. § 488.440(b).

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\$12,541 per-day CMP from June 14 through October 5, 2016, and a \$303 per-day CMP from October 6 through December 11, 2016. CMS Ex. 20 at 1-5.

Petitioner requested a hearing before an administrative law judge (ALJ) on March 20, 2017 (RFH). The case was assigned to me for hearing and decision on March 24, 2017, and an Acknowledgment and Pre-hearing Order was issued at my direction.

On July 16 through 18, 2018, a hearing was convened by video teleconference and a transcript (Tr.) of the proceedings was prepared. CMS offered CMS exhibits (CMS Exs.) 1 through 50, and CMS Exs. 1 through 47, 49, and 50 were admitted as evidence. Tr. 56-70, 306-07. CMS withdrew its offer of CMS Ex. 48, which remains in the record but is not considered substantive evidence. Tr. 210-15. CMS offered CMS Exs. 51, 52, and 53 post-hearing per agreement of the parties at hearing, and they are admitted. Tr. 1096-98. Petitioner offered Petitioner exhibits (P. Exs.) 1 through 31 that were admitted as evidence. Tr. 70-94, 944, 997, 1103.

CMS called the following witnesses to testify: Surveyor Raphaella Slade, RN; Kimberly Townsend, MPA, BSN, RN; and Itala Fontana, RN. The parties agreed to preserve the testimony of Sapna Bamrah Morris MD, MBA, CMS's expert witness, by deposition prior to hearing because she was unable to attend the hearing. Dr. Morris's declarations were admitted as CMS Exs. 42 and 46 and her deposition testimony as CMS Ex. 49.

Petitioner called the following witnesses: John Loome, MD; Funmi Odunubi, RN, Petitioner's director of nursing (DON); Suzanne Hayden, RN, Petitioner's Assistant DON (ADON) and infection control nurse;

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Bret Stine, Petitioner's administrator from approximately March to July 2015; Eduardo Salazar, Petitioner's administrator beginning in July 2015 for approximately two years; and Richard Hodder, MD. Following the hearing, the parties filed post-hearing briefs (CMS Br. and P. Br., respectively) and post-hearing replies (CMS Reply and P. Reply, respectively).

II. Discussion

A. Issues

Whether there is a basis for the imposition of an enforcement remedy;

Whether the declaration of immediate jeopardy is clearly erroneous; and

Whether the remedy imposed is reasonable.

B. Applicable Law

The statutory and regulatory requirements for participation of a SNF in Medicare are at section 1819 of the Social Security Act (Act) and at 42 C.F.R. pt. 483. Section 1819(h)(2) of the Act authorizes the Secretary to impose enforcement remedies against a SNF for failure to comply substantially with the federal participation requirements established by sections 1819(b), (c), and (d) of the Act.³ The Act requires that the Secretary terminate the Medicare participation of any SNF that does not return to substantial compliance with participation requirements within six months of the date noncompliance began. Act § 1819(h)(2)(C). The Act also requires that the Secretary deny payment of Medicare benefits for any beneficiary admitted to a SNF, if the SNF fails to return to substantial compliance with program participation requirements

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within three months of the date noncompliance began—commonly referred to as the mandatory or statutory denial of payment for new admissions (DPNA). Act § 1819(h)(2)(D). The Act grants the Secretary discretionary authority to terminate a noncompliant SNF’s participation in Medicare, even if there has been less than 180 days of noncompliance. The Act also grants the Secretary authority to impose other enforcement remedies, including a discretionary DPNA, CMPs, appointment of temporary management, and other remedies such as a directed plan of correction. Act § 1819(h)(2)(B).

The Secretary has delegated to CMS and the states the authority to impose remedies against a long-term care facility that is not complying substantially with federal participation requirements. “*Substantial compliance* means a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm.” 42 C.F.R. § 488.301 (emphasis in original). A deficiency is a violation of a participation requirement established by sections 1819(b), (c), and (d) of the Act or the Secretary’s regulations at 42 C.F.R. pt. 483, subpt. B. Noncompliance refers to any deficiency (statutory or regulatory violation) that causes a facility not to be in substantial compliance, i.e., a deficiency that poses a risk for more than minimal harm. 42 C.F.R. § 488.301. Therefore, even if a facility violates a statutory or regulatory requirement, CMS may not impose enforcement remedies if the deficiency does not pose a risk for more than minimal harm.

State survey agencies survey facilities that participate in Medicare on behalf of CMS to determine

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whether the facilities are complying with federal participation requirements. 42 C.F.R. §§ 488.10-.28, 488.300-.335. The regulations specify the enforcement remedies that CMS may impose if a facility is not in substantial compliance with Medicare requirements. 42 C.F.R. § 488.406.

CMS is authorized to impose a CMP against a facility not in substantial compliance with program participation requirements. The regulations specify that a CMP that is imposed against a facility on a per day basis will fall into one of two ranges of penalties. 42 C.F.R. §§ 488.408, 488.438. The upper range of a CMP, \$6,291 per day to \$20,628 per day, is reserved for deficiencies that pose immediate jeopardy to a facility's residents and, in some circumstances, for repeated deficiencies.⁴ 42 C.F.R. § 488.438(a)(1)(i), (d)(2); 45 C.F.R. § 102.3 (Table). "*Immediate jeopardy* means 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 (emphasis in original). The lower range of CMPs, \$103 per day to \$6,188 per day, is reserved for deficiencies that do not pose immediate jeopardy, but either cause actual harm to residents, or cause no actual harm but have the potential for causing more than minimal harm. 42 C.F.R. § 488.438(a)(1)(ii); 45 C.F.R. § 102.3 (Table).

The Act and regulations make a hearing before an ALJ available to a long-term care facility against

⁴ CMS increased the CMP amounts to account for inflation in compliance with the Federal Civil Penalties Inflation Adjustment Improvements Act of 2015, Pub. L. No. 114-74, § 701, 129 Stat. 584, 599 (2015). 81 Fed. Reg. 61,538, 61,549 (Sept. 6, 2016).

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which CMS has determined to impose an enforcement remedy. Act §§ 1128A(c)(2), 1866(h); 42 C.F.R. §§ 488.408(g), 498.3(b)(13). A facility has a right to appeal a “certification of noncompliance leading to an enforcement remedy.” 42 C.F.R. §§ 488.408(g)(1); 488.330(e), 498.3(b)(13). However, the choice of enforcement remedies or the factors CMS considered when choosing enforcement remedies are not subject to review. 42 C.F.R. § 488.408(g)(2). A facility may only challenge the scope and severity level of noncompliance determined by CMS if a successful challenge would affect the range of the CMP that may be imposed or impact the facility’s authority to conduct a nurse aide training and competency evaluation program (NATCEP). 42 C.F.R. § 498.3(b)(14), (d)(10)(i). The CMS determination as to the level of noncompliance, including the finding of immediate jeopardy, “must be upheld unless it is clearly erroneous.” 42 C.F.R. § 498.60(c)(2); *Woodstock Care Ctr.*, DAB No. 1726 at 9, 38 (2000), *aff’d*, *Woodstock Care Ctr. v. Thompson*, 363 F.3d 583 (6th Cir. 2003). The Board has long held that the net effect of the regulations is that a provider has no right to challenge the scope and severity level assigned to a noncompliance finding, except in the situation where that finding was the basis for an immediate jeopardy determination. *See, e.g., Ridge Terrace*, DAB No. 1834 (2002); *Koester Pavilion*, DAB No. 1750 (2000). ALJ review of a CMP is subject to 42 C.F.R. § 488.438(e).

The hearing before an ALJ is a de novo proceeding, that is, “a fresh look by a neutral decision-maker at the legal and factual basis for the deficiency findings underlying the remedies.” *Life Care Ctr. of Bardston*, DAB No. 2479 at 33 (2012) (citation omitted).

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The allocation of the burden of persuasion and the quantum of evidence required to meet the burden is not addressed by regulations.⁵ Rather, the Board has long held that the petitioner, the nongovernmental party, bears the burden of persuasion to show by a preponderance of the evidence that it was in substantial compliance with participation requirements or any affirmative defense. *Batavia Nursing & Convalescent Inn*, DAB No. 1911 (2004); *Batavia Nursing & Convalescent Ctr.*, DAB No. 1904 (2004), *aff'd*, *Batavia Nursing & Convalescent Ctr. v. Thompson*, 129 F. App'x 181 (6th Cir. 2005); *Emerald Oaks*, DAB No.

⁵ Congress granted the Secretary authority to impose enforcement remedies for noncompliance. Act § 1819(h)(2). The Secretary is authorized to impose CMPs as an enforcement remedy by section 1128A of the Act. CMPs are imposed by CMS with delegated authority of the Secretary. 42 C.F.R. § 488.2. Pursuant to subsection 1128A(j) of the Act, section 205 of the Act is applicable to the imposition of CMPs, and that section is applicable to the imposition of CMPs by both the Secretary and the Commissioner of Social Security under the authority of section 1128A of the Act. The Inspectors General (IGs) for both HHS and the Social Security Administration (SSA) also exercise delegated authority to impose CMPs pursuant to section 1128A of the Act. Both IGs engaged in rulemaking to specify the allocation of the burden of persuasion and the quantum of evidence required when proceeding upon a case involving a CMP. Both the SSA IG and the HHS IG imposed upon the government in CMP cases the burden of persuasion on all issues other than affirmative defenses and mitigating factors for which the burden is upon the nongovernmental party. The regulations of the IGs for SSA and HHS provide that the burden of persuasion is to be judged by a preponderance of the evidence. 20 C.F.R. § 498.215(b), (c); 42 C.F.R. § 1005.15(b), (d). CMS failed to promulgate a regulation similar to those of the HHS and SSA IGs, and the Board has filled the gap with its interpretative rules allocating the burden of persuasion to the nongovernmental party, the party defending against the imposition of the CMP.

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1800 (2001); *Cross Creek Health Care Ctr.*, DAB No. 1665 (1998); *Hillman Rehab. Ctr.*, DAB No. 1611 (1997) (remand to ALJ), DAB No. 1663 (1998) (after remand), *aff'd*, *Hillman Rehab. Ctr. v. United States*, No. 98-3789 (GEB), 1999 WL 34813783 (D.N.J. May 13, 1999). The Board has indicated that only when CMS makes a prima facie showing of noncompliance, is the facility burdened to show, by a preponderance of the evidence on the record as a whole, that it was in substantial compliance or had an affirmative defense. *Evergreene Nursing Care Ctr.*, DAB No. 2069 at 7 (2007). The Board has not specified how much evidence CMS needs to present to meet its burden of making a prima facie showing. The Board has stated that CMS must come forward with “evidence related to disputed findings that is sufficient (together with any undisputed findings and relevant legal authority) to establish a prima facie case of noncompliance with a regulatory requirement.” *Id.*; *Batavia Nursing & Convalescent Ctr.*, DAB No. 1904. “Prima facie” means generally that the evidence is “[s]ufficient to establish a fact or raise a presumption unless disproved or rebutted.” *Black’s Law Dictionary* 1228 (8th ed. 2004). One might conclude that if the preponderance of the evidence is required in these proceedings, that standard would also apply to the requirement for CMS to make a prima facie showing, that is, CMS should be burdened to present evidence sufficient to establish a fact as more likely true and to raise a presumption. However, the Board has never ruled that CMS must establish its prima facie case by a preponderance of the evidence. Indeed, it is unclear from prior Board decisions whether CMS can make a prima facie showing with little more than mere allegations or a scintilla of evidence. In this case, I conclude that

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CMS has made its prima facie showing by a preponderance of the evidence.

C. Findings of Fact, Conclusions of Law, and Analysis

My conclusions of law are set forth in bold text followed by my findings of fact and analysis. I have carefully considered all the evidence and the arguments of both parties, though not all may be specifically discussed in this decision. I discuss in this decision the credible evidence given the greatest weight in my decision-making.⁶ I also discuss any evidence that I find is not credible or worthy of weight. The fact that evidence is not specifically discussed should not be considered sufficient to rebut the presumption that I considered all the evidence and assigned such weight or probative value to the credible evidence that I determined appropriate within my discretion as an ALJ. There is no requirement for me to discuss the weight given every piece of evidence considered in this case, nor would it be consistent with notions of judicial economy to do so. Charles H. Koch, Jr., *Admin. L. and Prac.* § 5:64 (3d ed. 2013).

CMS alleges based upon the survey that ended October 6, 2016, that Petitioner was not in substantial compliance with program participation requirements from June 14, 2016 through December 11, 2016, based upon violations of 42 C.F.R. §§ 483.20(k)(3)(i) (Tag

⁶ “Credible evidence” is evidence that is worthy of belief. *Black’s Law Dictionary* 596 (8th ed. 2004). The “weight of evidence” is the persuasiveness of some evidence compared to other evidence. *Id.* at 1625.

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F281,⁷ scope and severity (s/s D⁸); 483.35(i) (Tag F371, s/s E); 483.65 (Tag F441, s/s K); and 483.70(h)(4) (Tag F469, s/s E).

Petitioner requested ALJ review of only the non-compliance cited as posing immediate jeopardy based on the alleged violation of 42 C.F.R. § 483.65 (Tag

⁷ This is a “Tag” designation as used in CMS Pub. 100-07, State Operations Manual (SOM), app. PP—Guidance to Surveyors for Long Term Care Facilities (<http://www.cms.hhs.gov/Manuals/IOM/list.asp>). The “Tag” refers to the specific regulatory provision allegedly violated and CMS’s policy guidance to surveyors. Although the SOM does not have the force and effect of law, the provisions of the Act and regulations interpreted clearly do have such force and effect. *Ind. Dep’t. of Pub. Welfare v. Sullivan*, 934 F.2d 853 (7th Cir. 1991); *Nw. Tissue Ctr. v. Shalala*, 1 F.3d 522 (7th Cir. 1993). Thus, while the Secretary may not seek to enforce the provisions of the SOM, he may seek to enforce the provisions of the Act or regulations as interpreted by the SOM.

⁸ CMS and the state agency use scope and severity levels when selecting remedies. The scope and severity level is designated by an alpha character, A through L, selected by CMS or the state agency from the scope and severity matrix published in the SOM, Chap. 7, § 7400E. A scope and severity level of A, B, or C indicates a deficiency that presents no actual harm but has the potential for minimal harm, which is an insufficient basis for imposing an enforcement remedy. Facilities with deficiencies of a level no greater than C remain in substantial compliance. 42 C.F.R. § 488.301. A scope and severity level of D, E, or F indicates a deficiency that presents no actual harm but has the potential for more than minimal harm that does not amount to immediate jeopardy. A scope and severity level of G, H, or I indicates a deficiency that involves actual harm that does not amount to immediate jeopardy. Scope and severity levels J, K, and L are deficiencies that constitute immediate jeopardy to resident health or safety. The scope and severity matrix, which is based on 42 C.F.R. § 488.408, specifies which remedies are required and optional at each level based upon the frequency of the deficiency.

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F441). RFH; Tr. 14-15. Accordingly, my review is limited to the alleged noncompliance under Tag F441 and the reasonableness of the CMP in the upper range of authorized CMPs based on the immediate jeopardy citation.

1. Petitioner did not request review of the noncompliance cited as violations of 42 C.F.R. §§ 483.20(k)(3)(i) (Tag F281) (s/s D), 483.35(i) (Tag F371) (s/s E), and 483.70(h)(4) (Tag F469) (s/s E); those citations of noncompliance are administratively final; and the citations are bases for the imposition of enforcement remedies.

2. Petitioner did not request review of the reasonableness of the \$303 per day CMP based on the unchallenged noncompliance citations for the period October 6 through December 11, 2016, and that remedy is administratively final and not subject to further review for reasonableness.

3. CMS has established a prima facie case that Petitioner was not in substantial compliance with 42 C.F.R. § 483.65.

4. Petitioner has not met its burden to show by a preponderance of the evidence that it was in substantial compliance with 42 C.F.R. § 483.65 during the period June 14 through December 11, 2016.

a. Facts

This case involves the occurrence of Tuberculosis (TB) in Petitioner's facility. Findings related to latent TB infection (latent TB infection) and active TB are

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set forth followed by findings of fact regarding the occurrence of TB in Petitioner's facility.

i. Latent TB Infection, Active TB, and Standard of Care

Centers for Disease Control and Prevention (CDC) Guidelines

The CDC issues recommendations and guidelines for controlling tuberculosis in the United States. In 2005, the CDC published a revision of its guidelines previously published in 1994, for preventing the transmission of TB in health-care settings. CMS Ex. 41 at 3. In 2005, the CDC also issued with the American Thoracic Society and the Infectious Diseases Society of America recommendations for controlling tuberculosis in the United States. CMS Ex. 53. The CDC is accepted as an authoritative and credible source for information on the cause and control of TB and its guidance is evidence of the standard of care.⁹

TB is an infectious disease that is caused by the bacterium *Mycobacterium tuberculosis* (*M. tuberculosis*). According to the CDC, *M. tuberculosis*, which is carried in airborne droplets, is spread by people who have pulmonary or laryngeal TB when they cough, sneeze, shout, or sing. TB is not normally spread by surface contact. However, *M. tuberculosis* can remain airborne on normal air currents in a building for a prolonged period and can spread throughout a room or building. Infection occurs usually within two to 12

⁹ The CDC has issued numerous guidelines and recommendations that are potentially applicable in this case. However, I consider only those offered as evidence by the parties.

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weeks when a person inhales the droplet with *M. tuberculosis*, at which point one tests positive when tested for TB. The CDC says that the probability for infection from *M. tuberculosis* is affected by the concentration of droplets carrying *M. tuberculosis* and the duration of exposure—the closer the proximity to one infected and the longer the exposure, the higher the risk for infection. CMS Exs. 41 at 6, 115-16; 42 at 2-3; 53 at 9. *M. tuberculosis* can attack any part of the body but generally attacks the lungs. There are two TB-related conditions, latent TB infection and TB disease also referred to as active TB. If not treated properly active TB can be fatal, and five percent of patients diagnosed in the United States each year with active TB are either dead when diagnosed or they die during treatment. CMS Ex. 42 at 2-3, 5. Active TB in the throat or lungs can be infectious while active TB in other parts of the body are generally not. Active TB is most likely to be spread among people who spend time together every day. CMS Ex. 42 at 3. Residents and staff of congregate settings such as long-term care facilities are among those at highest risk for exposure and infection. CMS Ex. 41 at 7. The CDC stresses that the treatment of latent TB infection is essential to control and eliminate TB because it substantially reduces the risk that *M. tuberculosis* will progress to active TB. CMS Ex. 41 at 55.

The following definitions from CDC guidance are important in this case:

Latent TB infection, often referred to as LTBI, is a condition in which a person is infected with *M. tuberculosis* but does not have active TB. People with latent TB infection are asymptomatic, do not feel sick,

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have a positive TB test but a negative chest x-ray for active TB, and do not transmit the disease. People with latent TB infection are at risk for progression to active disease. Treatment (referred to as preventative therapy, chemoprophylaxis, or prophylaxis) is indicated for those at risk for progression to active TB.

Active TB means that the disease caused by *M. tuberculosis* is clinically active. Infectious TB refers to active TB of the lungs or larynx. People with infectious TB have the potential to transmit the disease.

CMS Exs. 30 at 10; 41 at 46; 42 at 3-4; 49 at 126-29; 53 at 4, 12.

Persons at high risk for progression from latent TB infection to active TB include people infected with *M. tuberculosis* within the previous two years. CMS Exs. 41 at 7; 42 at 3; 53 at 12. It is not disputed that progression from latent TB infection to active TB can occur at any time after being infected. CMS Ex. 42 at 15. According to the CDC, approximately five percent of people with newly acquired latent TB infection progress to active TB within two years of exposure, if there is no intervention. CMS Ex. 53 at 37. Approximately five to 10 percent of people with latent TB infection who are not treated will develop active TB during their lifetime. CMS Exs. 30 at 7; 41 at 6; 42 at 3. The CDC says that people with latent TB infection should be treated absent compelling contraindications. Treating latent TB infection is easier than treating active TB and helps prevent the spread of TB. CMS Ex. 42 at 4, 6. The CDC recommends that directly observed therapy (i.e., a healthcare worker

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watches the swallowing of each dose and records administration) be used when possible. CMS Exs. 53 at 40; 41 at 8-9, 21. According to the CDC, directly observed therapy is the standard of care for treating active TB or latent TB infection. CMS Ex. 41 at 21, 56-57.

CDC recommendations for TB control in health care facilities include offering treatment, if not contraindicated, for residents with latent TB infection. CMS Ex. 53 at 60, 70. Health care facilities pose an increased risk for transmission of TB due to the congregate setting. CMS Exs. 30 at 9; 41 at 7, 29; 42 at 11; 53 at 17. Therefore, residents in SNFs and NFs are at increased risk for transmission of TB. According to the CDC, elderly residents in SNFs and NFs “are almost twice as likely to acquire TB as those living in the community.” CMS Ex. 53 at 60. The CDC recommends that nursing home residents with latent TB infection “should be offered treatment according to current recommendations” CMS Ex. 53 at 60.

Control of TB in nursing homes requires, among other things, prompt detection and diagnosis, isolation of those who are infectious, and initiating standard therapy. The CDC notes that there is evidence of the value of treating latent TB infection in elderly residents of nursing homes to prevent future outbreaks. CMS Exs. 41 at 86; 53 at 60, 70. There is evidence that treatment of latent TB infection can reduce the risk for death due to progression to active TB. CMS Exs. 32 at 5-6; 33 at 6.

CDC recommended strategies for controlling TB in the United States include identification of people with latent TB infection that are at risk for progression to

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active TB and treatment with an effective drug regime. CMS Exs. 30 at 8; 53 at 17. The preferred treatment for latent TB infection is nine months of isoniazid (INH), but other treatment regimens are characterized as acceptable alternatives. CMS Exs. 30 at 18; 41 at 55, 86.

The CDC states that by law suspected or confirmed TB in a patient or health care worker must be reported to the local or state health department “so that follow up can be arranged and a community contact investigation can be conducted.” CMS Ex. 41 at 38, 58. The CDC states that the responsibility for TB control and prevention in the United States rests upon public health officials, including federal, state, county, and local public health agencies. CMS Exs. 42 at 8; 53 at 22. According to the CDC, “the primary responsibility for ensuring the quality and completeness of all TB-related services rests with the jurisdictional health agency” CMS Ex. 53 at 25; P. Ex. 4 at 2, 7;¹⁰ P. Ex. 5 at 1-2.

Maryland Regulations and Guidelines

The Maryland Department of Health and Mental Hygiene issued the “Maryland TB Guidelines for Prevention and Treatment of Tuberculosis” in 2007. CMS Ex. 39. The Maryland state health department is accepted as a credible source, and its guidance is also evidence of the standard of care. Listed as a general objective in the Maryland guidelines, among others, is the provision of treatment for latent TB infection to “high-risk reactors.” CMS Ex. 39 at 10. The Maryland guidelines provide that it is the responsibility of the

¹⁰ P. Ex. 4 includes extracts from CMS Exs. 41 and 51.

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local health department to identify, evaluate promptly, and ensure an appropriate course of treatment is prescribed and completed for all people suspected of having TB. The policy provides that a private provider undertaking to treat one with TB is undertaking a public health function that includes prescribing an appropriate treatment regime and ensuring adherence to that regime until treatment is completed. CMS Ex. 39 at 10. Therefore, the Maryland guidance specifically recognizes the role of a private provider in treating one with TB. The Maryland guidelines recognize that residents of SNFs/NFs are at risk for infection and the recently infected are at risk for conversion from latent TB infection to active TB. The guidelines state that a decision to test for TB is a decision to treat, including recent contacts with TB infection and residents of SNFs/NFs. CMS Ex. 39 at 12-14. The purpose of treating latent TB infection is to reduce the chance a person with latent TB progresses to active TB. Treatment should be targeted to high-risk groups regardless of age, including the recently infected and those in SNFs/NFs. CMS Ex. 39 at 14, 19.

Maryland specifies that directly observed therapy is the standard of care for active TB. The Maryland guidelines do not specify that directly observed therapy is the standard of care for latent TB infection. Maryland specifies either INH or rifampin is used for treatment of latent TB infection for six or nine months depending on the treatment regime. CMS Ex. 39 at 20-21, 28-30, 59. Compliance with diagnosis, treatment, and quarantine is enforceable by law in Maryland. CMS Ex. 39 at 39.

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Maryland regulations applicable to Petitioner require that the facility medical director serve as a liaison with local health officials and public health agencies. CMS Ex. 38 at 10, 14 (Md. Code Regs. 10.07.20.11-1(G)(3)). Maryland regulations also require that a facility monitor residents for signs and symptoms of tuberculosis by performing an annual symptom review, and if signs and symptoms are detected, a physician is required to evaluate for TB in communicable form, notify the health officer within 24 hours if the physician suspects TB, and coordinate management of the resident and the resident's contacts with the health officer. The regulations require that the facility assess and manage a resident with possible TB in accordance with CDC guidelines. CMS Ex. 38 at 17 (Md. Code Regs. 10.07.02.21-2(b)(4)-(5)). In Maryland, a health officer is required to recommend appropriate treatment for latent TB infection. CMS Ex. 38 at 19 (Md. Code Regs. 10.06.01.21(B)(2)).

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ii. TB in Petitioner's Staff and Residents

2015 TB Outbreak¹¹ and Contact Investigation¹²

The parties proposed findings of fact and the evidence admitted shows that there is little dispute regarding the outbreak of active TB and latent TB infection in Petitioner's facility among staff and residents. I note that there is a dispute about whether Petitioner's medical director, Dr. Passi, or Petitioner's staff ever received recommendations or orders for treatment of latent TB infection identified in its residents from the county health department between the revelation of the outbreak in May 2015 and September 2016. I find based on the following summary of the evidence that no recommendations for treatment of latent TB infection were received by Petitioner from the county health department prior to September 2016. P. Exs. 26-27.

¹¹ CMS objected at hearing to characterizing the occurrence of active TB and latent TB infections at Petitioner as an outbreak. Tr. 233. Outbreak as used in this decision refers to the fact that the active and latent TB cases occurred in Petitioner's nursing home environment, suddenly, and unexpectedly; there is no evidence that TB usually occurred in Petitioner's facility; and there were multiple cases of active and latent TB. The use of the term in this decision is consistent with Dr. Hodder's explanation of the meaning of the term as a term of art. Tr. 686-88; CMS Ex. 53 at 41-42. Under CMS guidance to surveyors, one case of an infection that is highly communicable, is an outbreak. CMS Ex. 52 at 22. TB is highly communicable and the occurrence of TB at Petitioner's facility is correctly referred to as an outbreak.

¹² A contact investigation is the process of investigating potential contacts with one with active TB that was infectious or communicable, followed by testing to determine if those contacts were exposed to TB. CMS Ex. 53 at 6, 17, 36-41.

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On about March 10, 2015, Petitioner's administrator, Bret Stine, received a letter from the county health department informing him that a housekeeper, referred to as RC, was not cleared to work until further notice. Petitioner's Proposed Findings of Fact (PPFF) ¶¶ 62, 64; CMS' Proposed Findings of Fact (CPFF) ¶ 14; P. Ex. 1; CMS Ex. 14 at 34; Tr. 981. The letter did not reveal that employee RC had active TB, but Petitioner learned that fact about two months later, which would be sometime in May 2015. PPFF ¶ 66; CPFF ¶ 15; CMS Ex. 14 at 36; Tr. 982. The case of RC is referred to as an index case by the experts and parties.

On April 27, 2015, Petitioner learned that a second staff member, nursing assistant MA, was being treated for active TB. The county health department did not formally notify Petitioner of this second active case until May 2015. PPFF ¶¶ 68, 69; CPFF ¶ 16; CMS Ex. 14 at 37.

On about May 13, 2015, the county health department notified Petitioner that a resident who had been hospitalized and died a week or so earlier had had active TB. PPFF ¶ 78; CPFF ¶¶ 23, 24; Tr. 987-92.

Therefore, there is no dispute that in May 2015, Petitioner's management knew it had two employees infected with active TB and that a recently deceased resident had had active TB.

On May 15, 2015, county health department officials met with Petitioner's administrator Stine, DON Odunubi, medical director Dr. Passi, ADON Hayden, the medical director and regional vice president for Petitioner's operator Dr. Looome (May 15, 2015 meeting). PPFF ¶ 79; CPFF ¶¶ 24-26; P. Ex. 7. Petitioner's staff understood that the county health department

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officials stated that they would take the lead and guide Petitioner's response. The county health department officials informed Petitioner that all residents potentially exposed to TB from January to March 2015, should be tested for TB exposure. PPFF ¶ 84; Tr. 469-475, 478-79, 945-48. Petitioner was responsible to ensure all residents were tested. PPFF ¶ 85; CPFF ¶ 25; Tr. 994-96.

ADON Hayden testified that she understood from the discussion at the May 15, 2015 meeting, that Petitioner would be providing medications for treatment of residents with latent TB infection, but the specific medications to be provided were not discussed. She also understood that the county health department would provide specific directions, assist to complete testing, and recommend necessary medication for treatment of latent TB infection. PPFF ¶¶ 85-86; Tr. 996-1001.

Following the May 15, 2015 meeting, Petitioner's staff completed two rounds of testing for all residents not previously tested positive for TB exposure. Testing, which I infer was skin testing as the evidence shows that the county health department did the blood testing for residents for whom skin tests were contraindicated, showed 19 or 20¹³ residents with TB

¹³ Petitioner states there were about 19 (Tr. 142) or 20 residents who tested positive for TB exposure (PPFF, 94). CMS states there were only 19 (CPFF, 39). The SOD indicates that on about October 6, 2016, 20 residents were receiving treatment for latent TB infection. CMS Ex. 1 at 7. The SOD also alleges that 19 residents were identified as positive for latent TB in the initial round of testing in May 2015. CMS Ex. 1 at 10. P. Ex. 21 lists 26 residents identified in 2015 as exposed to TB and 18 of those are not listed as deceased when that document was prepared in 2016. Counsel for Petitioner stated that there were 19 residents.

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exposure, and a list was provided to the county health department. Chest x-rays showed that none of the residents had active TB at the time. The second round of testing, which I infer was both skin testing by Petitioner's staff and blood testing by the county health department, was completed in August 2015, except for blood tests for four foreign born residents. PPF ¶¶ 94, 99, 103-104, 116-20; CPFF ¶¶ 29-31, 33-35, 39; CMS Ex. 22 at 16-21; Tr. 1001-1022.

There is no dispute that a decision was made to delay prophylactic treatment of the latent TB infection cases until after the second round of testing of Petitioner's residents was completed. Both the county health department and Petitioner's staff were aware

Tr. 142. Petitioner's expert testified that there were 20 residents who tested positive for latent TB infection and received chest x-rays. P. Ex. 31 at 11, 19. The surveyor discusses only four residents in the SOD, Residents 1, 5, 6, and 7 (CMS Ex. 1 at 10-15), and CMS provided me only limited documentation from the clinical records of Residents 1 through 7. There is no need to resolve the disparate numbers as there is no question that in May and June 2015, Petitioner had at least 19 residents who had been exposed to TB but who had not progressed to active TB as reflected by a positive skin test but a negative chest x-ray. There is also no dispute that none of the 19 received prophylactic medication for latent TB infection between their identification in May 2015 and about August or September 2016 when treatment for latent TB infection began, except for Resident 4 whose case is discussed hereafter. It would have been helpful to have a single, accurate listing of residents tested positive in 2015 by skin and blood tests and a similar list for those tested positive in 2016, with an indication of why residents do not appear on both lists. It would have also been helpful to have a single exhibit that included copies of all test results, chest x-rays, and physician orders for treatment or copies of the residents' clinical records. However, the absence of such detailed evidence does not prevent a decision in this case on the bases discussed hereafter.

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of and agreed with that decision. Tr. 585-87, 633-34, 1065; PPFF ¶ 111; CPFF ¶ 32.

Resident 4's Treatment for Latent TB Infection

The evidence shows Resident 4 tested positive for TB on about May 25, 2015, and an x-ray was negative for active TB. CMS Ex. 8 at 15, 19, 36-37. "Symptom Surveillance for Tuberculosis" forms electronically signed by DON Odunubi direct annual monitoring only for Resident 4. CMS Ex. 8 at 38-39. Resident 4 tested positive again in October 2015, during preparation for a kidney transplant, and her physician ordered prophylactic medication that was administered by Petitioner's staff PPFF ¶ 121-123; CPFF ¶ 40; CMS Exs. 14 at 129; 28 at 2; P. Ex. 20. On November 5, 2015, ADON Hayden sent a facsimile to the county health department. Written on the facsimile cover sheet is information that Resident 4 was started on INH 300 mg per day and vitamin B-6 50 mg once per day. A progress note that was transmitted with the facsimile cover-sheet is dated October 28, 2015, and shows that Resident 4 was seen by an infectious disease physician due to testing positive for TB that was not active and he prescribed INH and vitamin B-6 on October 28, 2015. P. Ex. 20 at 1-2; Tr. 1059-60. There is no documentary evidence offered by either party that Resident 4 received INH beginning in October 2015. However, ADON Hayden testified the medication was administered as ordered. Tr. 1061. Clinical records for Resident 4 obtained by the surveyors show that on June 22, 2016, Resident 4 had a prescription for INH 300 mg, one time per day for latent TB infection. CMS Ex. 8 at 4, 29. It is not clear from the Physician's Order sheet whether the order was a new order or had been in place since October or November

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2015. Resident 4 was again tested for TB on August 30, 2016, and it was reported that there was no evidence of TB. CMS Ex. 8 at 21, 22, 40-45.

Other Residents with Latent TB Infection Were Not Treated

There is no dispute that no prophylactic treatment was started in 2015 or before September 2016 for any resident that tested positive for latent TB infection, except for Resident 4. Petitioner knew that no treatments for latent TB infection were provided to its residents who tested positive for latent TB throughout 2015 and until September 2016, except Resident 4. PPFF ¶¶ 132, 134, 135, 137, 139, 158; CPFF ¶ 40-41.

TB testing and the administration of prophylactic medication for latent TB infection was regularly discussed among Petitioner's staff and management from August 2015 through January 2016, and after. PPFF ¶¶ 125, 128-30; CPFF ¶¶ 43-47.

In May 2016, Petitioner's staff did an annual assessment of residents who had previously tested positive for exposure to TB in 2015, and staff found no signs or symptoms of active TB. PPFF ¶ 163; P. Ex. 21.

Resident 1's Conversion¹⁴ to Active TB and the 2016 TB Outbreak

Resident 1 tested positive for TB in May 2015, and a chest x-ray showed no active TB. PPFF ¶ 166; CPFF ¶ 50; CMS Ex. 5 at 29-30, 36, 77, 79, 87-88; Tr. 1025-26. Symptom Surveillance for TB forms indicate that effective May 9, 2015, the resident was on annual

¹⁴ Conversion refers to the undisputed fact that Resident 1 had latent TB infection and subsequently developed active TB.

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monitoring only. CMS Ex. 5 at 44-45. A year later, on June 4, 2016, Resident 1 had a chest x-ray. PPFF ¶¶ 170-176; CPFF ¶ 51; CMS Ex. 5 at 61. However, Resident 1's physician did not diagnose Resident 1 with active TB. PPFF ¶¶ 177-180; CMS Ex. 5 at 55-58, 62-72. On August 4, 2016, Resident 1 was coughing up blood. PPFF ¶ 182; CPFF ¶ 53; CMS Ex. 5 at 2. Resident 1's clinical records in evidence do not list a diagnosis of latent TB infection. Tr. 143-44. However, her records from May 29, 2015, do reflect a positive test for TB followed by a chest x-ray. CMS Ex. 5 at 29. On August 9, 2016, another chest x-ray resulted in the diagnosis of active TB. PPFF ¶¶ 182-183; CPFF ¶ 55; CMS Ex. 5 at 43, 46-48.

Due to Resident 1's diagnosis with active TB, Petitioner's staff contacted the county health department and testing of all employees and residents of Petitioner's facility began again. PPFF ¶ 184. Following the new testing, which was completed in September 2016, 16 residents were identified as having latent TB infection (including some that were positive in 2015), no active TB was identified, and prophylactic treatment was recommended or ordered beginning about September 15, 2016. PPFF ¶¶ 185-187; P. Exs. 22-27; CMS Ex. 14 at 236-42; Tr. 1069-70.

Active TB of Employee in 2015 and Active TB of Resident 1 Had Common Origin

The Maryland Department of Health and Mental Hygiene, at the request of counsel for CMS, compared a sample taken from housekeeper RC on March 10, 2015, and a sample from Resident 1 obtained August 9, 2016. The genotype matched indicating that there was likely a common origin for the TB. CMS Exs. 39 at 27; 46 at 4-6; 47; 53 at 14-16.

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Petitioner's TB Management Policy

Petitioner was not cited by the surveyor for not having an infection control policy and procedure as required by 42 C.F.R. § 483.65. There is no dispute that Petitioner had the required policy, extracts of which specifically related to TB are in evidence marked as P. Ex. 6.

Petitioner's tuberculosis management policy shows it became effective September 1, 2004, it was revised on October 1, 2013, and it was subsequently reviewed on September 1, 2015. P. Ex. 6 at 1. There is no dispute that this policy and procedure document was in effect in 2015 and 2016 during the TB outbreaks at Petitioner's facility. The document placed in evidence is composed of a policy statement (P. Ex. 6 at 1-2) followed by a procedure for TB screening (P. Ex. 6 at 3-5), and a separate procedure for addressing TB post exposure for residents (P. Ex. 6 at 6-7).

The policy statement provides that all residents are tested for TB on admission to Petitioner in accordance with CDC guidelines and Maryland law and recommendations. The policy statement provides that if TB exposure occurs in Petitioner's facility, management is to notify the health department and conduct an investigation in accordance with state guidelines. The policy provides that all residents are to be screened in accordance with state guidelines. The stated purpose of the policy is to reduce the risk for transmission of TB among residents and provide management if TB exposure occurs. P. Ex. 6 at 1. The policy sets forth practice standards in sections titled "screening" and "post exposure." The policy clearly addresses: (1) routine screening testing upon admission to Petitioner; and (2) the action required when it is determined that

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a resident has been identified as having been exposed to TB. The policy provides that when TB is identified (the policy does not specify active TB or latent TB infection) the health department is to be notified and its recommendations for investigation and follow-up are to be followed; an investigation is to be done to identify any residents or staff that have been exposed; and treatment needs of residents are to be determined. P. Ex. 6 at 1-2. I note that Petitioner's policy does not state that investigation and determination of treatment needs are to be accomplished by the health department, or suggest that Petitioner's staff must wait for those steps to be completed by the county health department.

Petitioner's TB screening procedure requires staff to review any hospital discharge summary of a resident being admitted to Petitioner for signs of TB. P. Ex. 6 at 3. I consider this requirement to reflect Petitioner's recognition that is important to clearly document in clinical records any evidence of TB, which could include active TB, or the results of testing reflecting latent TB infection. The procedure requires skin testing within 48 hours and within no more than 10 days for all new admissions, except in specified cases. The procedure specifies that for new admissions a first skin test is to be done and if it is negative a second test is to be done in one to three weeks. The policy specifies that if either skin test is positive, staff is to obtain a chest x-ray and medical evaluation is to be done. Staff is also instructed to observe for signs and symptoms of TB and obtain medical evaluations if signs and symptoms are present. If a resident is identified as having suspected or confirmed TB, steps to isolate and transfer the resident are specified. If

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the required chest x-ray is negative for active disease the procedure requires that: (1) symptoms of active TB are to be reviewed with the resident and the resident is to be monitored annually; (2) the resident is to report any signs or symptoms of active TB; and (3) staff is to observe for signs and symptoms of TB, which I construe, based on the CDC material described, to be active TB as latent TB infection appears to have no observable signs and symptoms, other than a positive skin test and negative chest x-ray. In section 4 of the procedure, it is specified if at any time a resident develops signs and symptoms of TB, which arguably should include a positive skin test, staff is to obtain a chest x-ray and initiate medical evaluation. If the chest x-ray and/or medical evaluation is negative for active disease, alternative diagnoses are to be considered and the resident evaluated for chemoprophylaxis, which I construe to be treatment for latent TB infection. P. Ex. 6 at 3-4. Petitioner's TB screening procedure does not state that testing, medical evaluation, and determination of whether treatment is appropriate are to be accomplished by the health department, or suggest that Petitioner's staff must wait for those steps to be completed by the county health department. P. Ex. 6 at 3-5.

Petitioner's post TB exposure procedure for residents provides that as soon as TB exposure is identified (no distinction is made between active TB and latent TB infection), the health department is to be notified and its recommendations for investigation and follow-up are to be followed. P. Ex. 6 at 6. The procedure requires staff to investigate and to identify any residents or staff who have been exposed to TB. The

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procedure requires that skin testing, except in specified cases, proceed, ideally with two weeks of possible TB exposure. If the results of the first skin test are negative, a second test is done within 12 weeks after exposure. If a skin test is positive, the procedure is to obtain a chest x-ray and medical evaluation. Although the organization of sections of the procedure is confusing, the procedure specifies that when a chest x-ray and/or medical evaluation is negative for active disease, staff is to proceed to obtain an evaluation for chemoprophylaxis. P. Ex. 6 at 5-7. Petitioner's procedure does not state that staff is to wait to follow the procedure, including skin testing, chest x-rays, medical evaluation, and evaluation for treatment of latent TB infection, until the health department makes its recommendations for investigation and follow-up.

Petitioner's infection control policy and procedures related to TB do not specifically mention notification of a resident's treating physician, but I find it more likely than not that the medical evaluations and evaluations for chemoprophylaxis should be read to suggest that those evaluations include the treating physician. The policy and procedures clearly do not state that a medical evaluation or evaluation for prophylaxis was to be performed by county health department officials. The policy and procedures clearly direct facility staff to obtain the evaluations and the most likely source for such an evaluation would be the resident's treating physician.

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Witness Testimony¹⁵

Kimberly Townsend, MPA, BSN, RN was called by CMS and testified by declaration subject to cross-examination at hearing. RN Townsend was a nurse administrator for the county health department. She testified regarding the meeting she and RN Fontana attended with Petitioner's staff in May 2015. She testified the purpose of the meeting was to provide Petitioner's staff direction regarding a contact investigation following possible exposure of staff and residents to active TB. She testified that it was explained to Petitioner's staff that staff members had the option of obtaining TB testing from the county health department or their own primary physician, but Petitioner was responsible for care and treatment of its residents, including testing and follow-up treatment. She

¹⁵ Although the parties agreed to most of the relevant facts, they presented witness testimony rather than simply stipulating to the undisputed facts. In this case, the witness testimony is particularly helpful for me to better understand the extremely complex issues related to TB, its identification, and treatment. For that reason, a summary of the relevant testimony is included in this decision, with weight and credibility determinations noted. No significant issues of credibility are identified, and all witnesses generally provided credible testimony except where noted. However, as addressed for certain witnesses, the weight of witness testimony is significantly affected by knowledge of the facts, including CDC guidance and Maryland law, which is set forth in some detail in this decision. Witness testimony is also summarized here as my findings of what they testified to. This is particularly necessary in this case given a significant number of errors and omissions in the transcript due to the inadequacy of microphones used during this video conference hearing, and the need to clarify with witnesses when questions and responses were muddled or confused.

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testified that it was agreed that Petitioner would handle most testing, but Petitioner's staff requested assistance with obtaining blood testing. RN Townsend testified it was explained to Petitioner's staff that the goal was identification and treatment of individuals with active TB and those with latent TB infection. She testified that it was explained that the county health department recommended prophylactic treatment for anyone who had a positive TB test and treatment would be provided by Petitioner. Monitoring of affected residents was also emphasized. She testified that Petitioner's staff verbalized agreement and understanding. CMS Ex. 44; Tr. 472-74, 478-80, 490-91. RN Townsend testified that she and RN Fontana had a conference call with Petitioner's medical director at the time, Dr. Passi, probably in May 2015. During the conference call, treatment for latent TB infection was discussed and she believed he understood that isoniazid (INH) and vitamin B6 were usually used for nine months. Tr. 526-29. RN Townsend testified that under Maryland law the county health department was only responsible for oversight of active TB cases not cases of latent TB infection. She testified that the occurrence of latent TB infection is not something that must be reported to the county health department and only active TB cases are reportable. Tr. 515-16. RN Townsend's testimony regarding the county health department's involvement with latent TB infection cases is at odds with the Maryland guidance and regulations, and is not accepted as weighty.

RN Townsend testified that the county health department took the unusual step of having a county physician write individual treatment recommendations for each affected resident after the second round

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of testing of residents was completed in September 2015. RN Townsend was clearly unaware that in Maryland a county health officer is required to recommend appropriate treatment for latent TB infection. CMS Ex. 38 at 19 (Md. Code Regs. 10.06.01.21(b)(2)). However, RN Townsend testified that the recommendations were only in written form and after they were sent to Petitioner by facsimile, they could not be located. CMS Ex. 44, Tr. 493-504, 510-12, 530-31. I find RN Townsend's testimony regarding preparation and transmission of treatment recommendations credible. Her testimony is consistent with an October 26, 2015 email she sent that indicates recommendations were sent to Petitioner's medical director. CMS Ex. 48 at 38-40. However, RN Townsend did not testify in her declaration when the recommendations were sent or to any knowledge that the individual recommendations were actually received by Petitioner's medical director or Petitioner's staff RN Townsend did not testify that there was any attempt to verify Petitioner's receipt of the treatment recommendations. There is also no evidence that RN Townsend, RN Fontana, or the county health officer explained that Maryland specifies either isoniazid (INH) or rifampin is used for treatment of latent TB infection for six to nine months depending on the treatment regime. CMS Ex. 39 at 20-21, 28-30, 59. Advising Petitioner's staff of the Maryland policy on treatment for latent TB infection may not have satisfied the Maryland regulatory requirement that the health officer provide treatment recommendations for latent TB infection. However, it is surprising that county health department staff did not advise Petitioner's staff that there were only two choices of treatment under Maryland guidelines, either isoniazid (INH) or rifampin, with a preference

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under CDC guidelines for isoniazid (INH), and that information should be shared with primary care physicians so that treatment could be ordered. RN Townsend testified that Petitioner's staff advised the county that they intended to start treatment for latent TB infection after a second round of testing of residents was finished in September 2015, but no treatment was started and Petitioner's staff advised that they were waiting due to a change in Petitioner's administrator. Tr. 497-503. RN Townsend testified the Maryland regulations make a facility responsible for the care and treatment of facility residents. CMS Ex. 44 at 2.

RN Townsend testified that she learned from RN Fontana in November 2015, that treatment for latent TB infection had not been started, but she was not concerned because Petitioner's staff had done a good job with the contact investigation and she believed treatment would begin when Petitioner's new medical director was in place. She agreed on my examination that she did no follow-up with Petitioner's staff about whether treatment was initiated after November 2015, but she thought RN Fontana had continuing communication with ADON Hayden. Tr. 508-09, 512-15. RN Townsend testified that she was not aware that treatment for latent TB infection had not been started until Resident 1 was diagnosed with active TB. Tr. 531-32.

RN Itala Fontana was called by CMS and testified. RN Fontana is a community health nurse with the county health department. In her position, she serves as case manager for cases of active TB. Tr. 557-60. She became aware of the cases of Petitioner's two employees who had active TB in 2015 and of the resident

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who previously died due to TB. She was assigned to do the contact study related to those cases by her supervisor, RN Townsend. She participated in the May 15, 2015 meeting with Petitioner's staff and medical director, and RN Townsend. Tr. 562-68. She testified it is rare for the county health department to make treatment recommendations for treatment of latent TB infection. RN Fontana was clearly unaware of the requirement of the Maryland regulation that the county health officer recommend appropriate treatment for latent TB infection. CMS Ex. 38 at 19 (Md. Code Regs. 10.06.01.21(b)(2)). She testified that in her opinion the medical director for the facility or the primary care physician should know that their resident is infected and order treatment. She testified that the standard of care is to administer isoniazid (INH) and vitamin B6 for nine months. Tr. 580-81. She testified that during a conference call with her, RN Townsend, and Petitioner's medical director, the medical director expressed that he understood the treatment protocol. Tr. 583-84. She testified that the county physician did send treatment recommendations about the third or fourth week of October 2015. Tr. 584-85, 588-90. She testified that Petitioner did not need to receive treatment recommendations from the county physician as treatment recommendations are in the CDC guidelines. She did not mention that Maryland guidelines also specify treatment protocols for latent TB infection. CMS Ex. 39 at 20-21, 28-30, 59. She testified that normally the facility medical director or physician for the resident would be notified that the resident had latent TB infection and he or she would determine what medication to use, subject to refusal by the resident or family. If treatment was re-

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fused, then the facility would have to monitor the resident with latent TB infection monthly for at least a year for symptoms of active TB. Tr. 590-92. She testified that she sent treatment recommendations to Petitioner by facsimile. She did not testify, however, that she knew that the recommendations were received by Petitioner. She did not testify that she attempted to verify receipt of the recommendations in any way. She testified that ADON Hayden did not tell her that she did not receive the recommendations, but clearly she did not ask. She testified that the recommendations and the facsimile sheet were lost when the county health department moved. Tr. 597-98. While I accept as true her testimony that she sent the treatment recommendations to Petitioner by facsimile, her testimony does not establish that the recommendations were actually received. She testified that she learned on November 5, 2015, that Petitioner had not started treatment for any resident with latent TB. She was aware that one resident had treatment in conjunction with preparing for a kidney transplant, but it is not clear when she learned that. On January 26, 2016, she again communicated with ADON Hayden and was aware that treatment for residents with latent TB infection had not begun. Tr. 607-16. In August 2016, she learned that Resident 1 was showing symptoms of active TB. She testified that had ADON Hayden informed her of Resident 1's symptoms in June 2016, she would have told her to have the resident evaluated for TB. Tr. 620-22. On cross-examination, she agreed that not all residents had received required blood tests by November 2015 or January 2016. She also agreed that in November 2015, she agreed with ADON Hayden to setting a

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meeting with Petitioner's new medical director, but she did not follow-up with that. Tr. 634-38.

Bret Stine testified that he was Petitioner's administrator from approximately March to July 2015. Tr. 776-77. He testified based on his 35 years as a nursing home administrator in Maryland with frequent interactions with Maryland county health departments, that he understood the nursing home is responsible to report to the county health department and the health department provides guidance and takes the lead directing action by the nursing home. He testified that Petitioner's policy (P. Ex. 6 at 1) is that in the case of TB, the county health department was to be notified and its recommendations for investigation and follow-up were to be followed. Tr. 780-84, 801. He testified he attended the May 15, 2015 meeting. County representatives told Petitioner's staff in attendance that the county would guide staff through the process including staff education, which occurred during a later meeting. His understanding was that the health department would collaborate with conducting the contact investigation and throughout the entire process. He testified that Petitioner's medical director, Dr. Passi, also attended the May 15, 2015 meeting. He recalled that Dr. Passi indicated he would be following the health department direction. Tr. 789-93. He testified that no treatment recommendations were received from the county prior to his departure from Petitioner in July 2015. Tr. 793. He agreed in response to my questioning that he would expect that a positive test for TB exposure would be documented in a resident's clinical record. Tr. 797.

Eduardo Salazar testified that he became Petitioner's administrator when Mr. Stine departed in

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July 2015 and he continued in that role until the end of 2016. Tr. 809-12. He was briefed on the situation with TB when he took over. Tr. 813. He testified that Dr. Passi was medical director until about November 2015, and was followed by Dr. Ajani in that role. Tr. 814-15. He testified that Dr. Passi and later Dr. Ajani attended monthly quality assurance committee meetings he also attended at which the TB outbreak was discussed. Tr. 815, 822. Mr. Salazar testified that ADON Hayden was the infection control nurse throughout the entire period of the TB outbreak. He testified he was aware of no written or oral direction from the county health department for treatment of residents. He recalled that it was explained to him when he took over that they were following the direction and guidance of the county health department for handling the TB outbreak and they were waiting for further guidance. He testified that they continued to wait until August 2016, when the second contact investigation started, which was triggered by Resident 1 developing active TB. Tr. 816-18. In response to my question he stated he was not certain that a TB test result would be recorded in a resident's clinical record. Tr. 818-21.

John Loome, MD, testified. He is the senior vice-president of medical affairs for Genesis Healthcare, East Division, which is the manager and operator of Petitioner. Tr. 845-49. He provides oversight and guidance to medical directors of approximately 125 facilities operated by Genesis. Tr. 849-50. He testified that TB is insidiously contagious so that everyone in Petitioner's facility was at risk when employees had active TB in the spring of 2015, and there was also risk for the community. Therefore, the county health

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department had to be involved. He agreed that there is a legal requirement to notify the county health department and it is standard of practice to do so. Tr. 854-57. He opined that if one has latent TB infection or active TB, it is the responsibility of the county health department to ensure that an investigation is done and treatment provided. Tr. 864. He opined that it is the county health officer's responsibility to recommend a course of treatment for latent TB infection. Tr. 868-76; CMS Ex. 38 at 19. He testified that Genesis policy is that facility staff must contact the county health department and follow their lead and direction. Tr. 877. He testified that he attended the May 15, 2015 meeting with Dr. Passi, Petitioner's medical director, some of Petitioner's staff, and representatives of the county health department. He discussed the meeting with Dr. Passi thereafter, and they both believed that the county health department would give recommendations and direction for residents with latent TB infection. Tr. 878-86; CMS Ex. 38. On cross-examination, he testified that he did not recall Dr. Passi or other staff stating that they had trouble contacting or obtaining information from the county health department during the period May 2015 to August 2016. He stated that his only involvement during the period May 2015 to August 2016, was attending the meeting on May 15, 2015. Tr. 894-96. He testified that he first learned in October 2016, that the health department had not provided information requested by Petitioner's staff when he spoke with Dr. Passi who he agreed was not Petitioner's medical director at the time. Tr. 906-08. Dr. Looome testified on cross-examination that he participated in selecting Dr. Ajani to succeed Dr. Passi as Petitioner's medical director in October 2015. He testified that Dr. Ajani was aware

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of the TB outbreak at Petitioner when he took the position. Tr. 923-24.

DON Odunubi was called to testify by Petitioner. Tr. 940. She testified that her understanding from meetings with county health department staff at Petitioner on May 15, 2015 and June 11, 2015, was that the county staff would instruct them on the plan of care for residents and staff at Petitioner. Her understanding of Petitioner's infection control policy was that they were to notify the county health department and to follow the county recommendations for investigation and follow-up. She testified that no written guidance or recommendations for treatment of latent TB infection were received from the county between May and November 2015. She testified that RN Fontana never told her that recommendations for treatment of latent TB infection had been faxed. Tr. 946-49, 951. She testified on cross-examination that she recalled no communication between her and the county health department other than the meetings in May and June 2015. Tr. 954. DON Odunubi testified that it was not Petitioner's practice to update a care plan in the case of a positive TB test with a negative chest x-ray, unless treatment is initiated. She testified that Resident 4's care plan was updated when she began treatment and so were the care plans of residents for whom treatment was initiated in the fall of 2016. Tr. 1075-77. She testified that it was not the practice of physicians at Petitioner's facility to enter a diagnosis of latent TB in a resident's clinical record. According to DON Odunubi, if a resident tests positive for TB exposure and has a negative chest x-ray, Petitioner's staff simply monitors for symptoms of active

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disease.¹⁶ Tr. 1086-88. DON Odunubi did not explain how staff was to know to monitor for signs and symptoms of active TB if there was no care plan or even a diagnosis listed in the resident's clinical records. DON Odunubi's suggestion that only monitoring of a resident with latent TB infection is all that is required is clearly at odds with CDC guidelines (CMS Ex. 53 at 60; P. Ex. 4 at 7), Maryland guidelines (CMS Ex. 39 at 12-14, 19), and Petitioner's TB management policy (P. Ex. 6). On cross-examination, DON Odunubi agreed that patients with a positive TB test and negative chest x-ray should be treated. Tr. 1094.

¹⁶ Petitioner was not cited with noncompliance because its infection control policy was inadequate or due to inadequate care planning to treat and/or monitor latent TB infection. However, the example of Resident 1 clearly shows why Petitioner's policy, at least as interpreted by DON Odunubi and ADON Hayden, was inadequate to prevent or control outbreaks for TB. Resident 1 was identified in May 2015 by a positive TB skin test and negative chest x-ray as having a latent TB infection. Resident 1 was not treated for latent TB infection and was formally evaluated in May 2016, a year after initial identification, and determined not to have converted to active TB. One month later Resident 1 had signs and symptoms consistent with possible active TB that were not recognized as such, an oversight that may have been facilitated by the fact that Resident 1's records did not clearly reflect the TB testing in 2015 and the latent TB infection, either by a clear diagnosis or a care plan for the latent TB infection. If Petitioner's policy required clear documentation in resident records that the resident had a positive test and negative chest x-ray indicating probable latent TB infection, and a plan for treatment of latent TB and monthly assessments until the resident again tested negative for TB or the presence of latent TB infection was otherwise ruled out, Petitioner's policy would have much more effectively provided for the prevention and control of infections in the facility.

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ADON Hayden was called to testify by Petitioner. Tr. 970-71. She testified that in her capacity as infection control nurse she was responsible for monitoring both staff and residents for TB. Tr. 971-72. She testified that as an RN she had no authority to order testing or treatment. Tr. 976. She testified that she recalled that during the May 15, 2015 meeting with the county health department representatives there was a question about whether the county health department would be providing medications and the answer was that Petitioner would provide the medications. Tr. 996. She testified that she understood based on comments from RN Townsend that the county would take the lead and guide Petitioner throughout the process, including providing specific directions, helping with testing, and recommending medications for treatment of latent TB infection. Tr. 998. She testified that the county was requested to make recommendations for the type of medication and duration of treatment for latent TB infection. Tr. 1000. ADON Hayden testified that in order for chest x-rays to be performed for residents with a positive skin test for TB exposure, it was necessary to obtain a physician's order. When the chest x-rays were done, the results were sent to the physician to give any additional orders. All the chest x-rays performed for residents were negative. Employees identified by a positive skin test for TB were handled by the county health department. Tr. 1009-13. She clarified that skin testing was ordered by Petitioner's medical director and chest x-rays were ordered by individual physicians. I accept her testimony as true. However, ADON Hayden did not explain why individual physicians were not asked to order treatment for latent TB infection when they were provided the chest x-rays that they

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ordered because their patients had a positive skin or blood test for TB. The medical director was not the treating physician for all the residents and there were three other attending physicians at the time. The medical director also issued orders for blood testing requested by the county health department. Tr. 1020-22. She testified that before he departed as medical director, Dr. Passi asked whether she had received treatment recommendations for the county health department. ADON Hayden testified she received no treatment recommendations from RN Fontana by facsimile in 2015. Tr. 1022-24.

ADON Hayden testified regarding Resident 1, and some of the resident's clinical records from June 4, 2016 to August 2016, are in evidence as P. Ex. 10. ADON Hayden testified that Resident 1 had a positive skin test for TB followed by a negative chest x-ray during the first round of testing in May 2015, but that is not reflected by the few documents from the resident's clinical record in evidence. She testified that Resident 1 had no signs or symptoms of active TB in May or June of 2015. The resident did have a history of emphysema and chronic obstructive pulmonary disease and other diagnoses before May 2015. ADON Hayden testified that Resident 1 had a change of condition on June 4, 2016. Tr. 1024-31, 1055. In response to my questions, she agreed that when Resident 1 had a positive TB skin test and a negative chest x-ray, the resident had latent TB infection. She was not aware whether Resident 1 was considered to have a change in condition in 2015 when testing showed she had latent TB infection. She agreed that nursing notes from June 2016 (P. Ex. 10 at 1-4) do not indicate that the resident had latent TB infection. She testified that

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staff may not have focused on the resident immunization status where the positive skin test would have been documented. She did not believe that latent TB had been added to the resident's "face sheet," a document which follows a resident when transferred to a hospital. She testified that she did not believe latent TB infection was entered on the face sheet of any resident. She also testified that she did not believe that the interdisciplinary team for any resident updated a resident care plan based on the fact that testing showed a resident had latent TB, and she agreed she would have been involved in care planning related to infection control. She testified that updating resident face sheets and care plans would involve no direction or guidance from the county health department. Tr. 1032-39. ADON Hayden testified that a determination that a resident had latent TB infection would trigger a care plan update for symptom surveillance. She testified that symptom surveillance was done, but she was not aware of any care plans being updated for any residents in 2015. Tr. 1039-40, 1045. She did not explain how staff was to know to do symptom surveillance without a diagnosis in the resident's clinical record or a care plan. She testified that ordinarily a nurse would not question a physician's diagnosis or treatment order, unless there was an obvious issue. Tr. 1049.

ADON Hayden testified regarding Resident 4. Resident 4 required treatment for latent TB infection before undergoing a kidney transplant. On November 5, 2015, ADON Hayden reported to RN Fontana at the county health department that Resident 4 had treatment for latent TB infection ordered by a physician at the institution where the transplant was to be done

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(P. Ex. 20). She testified the treatment was administered by Petitioner's staff. Tr. 1059-61.

ADON Hayden testified that she told RN Townsend that she wanted to put off any treatment for residents with latent TB infection until the second round of testing of residents was complete. She testified that RN Townsend agreed. She testified that she did not have the discussion with RN Fontana, contrary to RN Fontana's testimony. Tr. 1065. She testified that when RN Fontana asked on November 5, 2015, whether treatment of residents with latent TB infection had begun, the second round of testing was complete except for the four residents who required blood draws that were difficult draws. She testified that she did not have further discussion regarding the question. Tr. 1066-67. She testified that she expected RN Fontana to get in touch with her because she knew that the county health department was making a move and latent TB is not contagious. She testified that Petitioner just continued to do symptom surveillance. Tr. 1067-68. After Resident 1 was diagnosed with active TB in August 2016, resident testing and chest x-rays were done again. Thereafter the county nurse practitioner and county physician issued orders for the treatment of latent TB infection with INH and vitamin B6 with liver function tests. Tr. 1069-71.

Expert Testimony and Opinions

Commander (CDR) Sapna Bamrah Morris, MD

The parties agreed to take the deposition of the CMS expert witness CDR Morris with the Public Health Service, in advance of hearing due to her unavailability during the scheduled hearing. Her deposition was admitted without objection as CMS Ex. 49

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and her declarations as CMS Exs. 42 and 46. CMS offered CDR Morris as an expert in the management of public health TB prevention and control programs. CMS Ex. 49 at 4-5. Based on consideration of CMS Ex. 42 pages 1, 2, and 16 through 30, I conclude CDR Morris is an expert in the area of disease prevention and control, specifically TB, and well-qualified to render expert opinions in that area (Tr. 1109). *See* Fed. R. Evid. 702-704.

CDR Morris opined based on the evidence that she reviewed from this case, that TB had been transmitted to identified residents. However, Petitioner failed to document whether those residents were eligible for treatment of latent TB infection. CMS Ex. 42 at 11-12. Her opinion is credible and weighty as Petitioner has conceded that, while the resident's records reflect positive TB tests and chest x-ray results, they contain no diagnosis of latent TB infection or determination by anyone qualified as to whether treatment was appropriate or contraindicated. Tr. 142-45; 295-96. CDR Morris opined that because residents with tests indicating latent TB infection were not treated, they were at risk to progress or convert to active TB, which is what happened to Resident 1. She opined that Resident 1 was not properly isolated or evaluated for active TB when symptoms appeared, placing staff and residents at risk. CMS Ex. 42 at 12. CDR Morris opined that in April and May 2015, after learning about two staff with active TB, Petitioner acted appropriately by contacting the county health department and doing a contact investigation as directed, and identifying staff and residents who had contact with the two infected employees. Appropriate TB tests were administered followed by chest x-rays. CDR

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Morris opined that the residents should have been diagnosed as having latent TB infections not later than September 2015. She opined that all residents assessed as having latent TB infection should have been offered and treated for latent TB infection absent a contraindication that should have been documented in their clinical record. CMS Ex. 42 at 12-15, 119. CDR Morris opined that in lieu of treatment for latent TB infection, a strict monitoring protocol should have been initiated, but there is no documentation in the files of Residents 1, 5, 6, or 7 that there was active surveillance of the type she describes with periodic symptom screening, physical examination, and chest x-rays. CMS Ex. 42 at 13. The parties provided me with only limited records for the four residents, so it is not possible for me to assess the weight to be assigned to CDR Morris' opinion that there is no documentation in the resident files of active surveillance.

CDR Morris opined that Resident 1 had symptoms consistent with active TB in May and June 2016, but was not diagnosed until August 2016. Between June and August 2016, Resident 1 posed a risk for TB infection to other staff and residents. CMS Ex. 42 at 14.

On cross-examination, CDR Morris clarified that her opinion that the documentation of follow-up of residents who tested positive for latent TB infection was inadequate, was based on the standard of care applicable to management of TB and she had no idea how that related to the applicable standard of care in the long-term care facilities. CMS Ex. 49 at 14-15. She testified on cross-examination that practitioners from county health departments do not generally write orders in healthcare settings. Health department physicians or their extenders would only write orders for

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those they see in their own clinic. CMS Ex. 49 at 37. CDR Morris testified that the testing procedure followed by Petitioner in May through August 2015, was acceptable. The two active staff cases were identified. Resident contacts with the two active cases were tested. Those residents who tested positive were given a chest x-ray to rule out active TB and then were ready for treatment for latent TB infection. Residents who tested negative were given a second test eight to 10 weeks later in August 2015. Those who tested positive had active TB ruled out by a chest x-ray and they were then ready for treatment for latent TB infection. Residents who had a second negative test did not have latent TB infection. She testified it was acceptable to delay treating the group identified in May 2015 as requiring treatment until the August 2015 group was identified so that all were treated as a cohort. CMS Ex. 49 at 53-54. CDR Morris testified that the infection control nurse and physician should know when treatment for latent TB infection is appropriate based on the CDC guidance. She agreed that a physician or practitioner needed to issue the order for treatment and that there may be contraindications for treatment. CMS Ex. 49 at 56. CDR Morris testified that an order for treatment would not be issued by a county health department but by the treating physician because a county health department would not have access to a resident's entire medical history. The only exception she noted is if the resident went to a county health department and was evaluated. CMS Ex. 49 at 57-60, 67. She clarified that the health department medical director would know about the source case of TB and could advise Petitioner whether standard prophylaxis medications could be used and which residents should be considered for treatment. However,

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Petitioner could have proceeded absent advice from the county medical director as was often done. CMS Ex. 49 at 85-86. She testified that the facility should have known the correct procedures for residents based on the CDC guidelines, educational materials that discuss the standard of practice, Maryland state regulations, and the TB infection control plan. CMS Ex. 49 at 67. CDR Morris further clarified that latent TB infection is not a condition that is reportable to the public health authority which has no authority over latent TB infection, even if there is a high risk for infection. CMS Ex. 49 at 77, 130-31. CDR Morris was apparently unfamiliar with the Maryland regulation that requires a health officer to recommend appropriate treatment for latent TB infection. CMS Ex. 38 at 19 (Md. Code Regs. 10.06.01.21(b)(2)).

CDR Morris testified on cross-examination regarding Resident 1, that she had a positive TB test in May 2015 and a negative chest x-ray indicating that she had latent TB infection and not active TB. The resident's baseline testing on admission to Petitioner showed she had a negative TB test, which is evidence that her exposure to active TB was recent and likely Petitioner's employee was the index that was infectious. CDR Morris could find no information in the evidence she was given showing that Resident 1 was informed, educated, and offered treatment for latent TB infection, or whether she accepted or refused treatment. She found no evidence of treatment after the resident tested positive for latent TB infection in 2015, and it is known she did not receive treatment at that time. CDR Morris opined Resident 1 was at high risk in the first two years after exposure and she

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should have received treatment for the latent TB infection or have been monitored closely for symptoms consistent with active TB. In June 2016, Resident 1 developed a cough and complained of chest pain, and a chest x-ray was done showing classic signs of active TB, which should have caused a medical evaluation to rule out TB. The resident's physician diagnosed bronchitis which was inconsistent with the x-ray findings. She further opined that Petitioner's infection control nurse should have recognized the symptoms of possible active TB if she was monitoring the resident. She opined that Petitioner's staff should have alerted Resident 1's physician of her risk for developing active TB. CMS Ex. 49 at 91-102, 105-11.

CDR Morris testified that it is standard of care to provide treatment for latent TB infection. CMS Ex. 49 at 131. It is also necessary for a resident's caregiver to be informed of the latent TB infection. CMS Ex. 49 at 134-36. CDR Morris testified that there is no requirement for a healthcare facility such as Petitioner to wait for direction from the county health department on how to proceed to treat latent TB infection. CMS Ex. 49 at 163-66. She testified that those living in a congregate setting with latent TB infection should be treated unless there is a contraindication or they refuse treatment in which case they should be monitored for two years if there was a recent exposure. She opined that the fact Resident 1 had an exposure and within two years developed symptoms of active TB that were not identified by Petitioner's staff, indicates that monitoring was not being done. When on or about June 4, 2016, Resident 1 showed signs and symptoms consistent with possible active TB, she should have been isolated under both CDC and state

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guidelines. CMS Ex. 49 at 166-70. She opined that Resident 1 was at risk for possible death because of the delay in diagnosis of active TB. Other residents were also at risk for progression to active TB which can be life-threatening. CMS Ex. 49 at 188.

Richard A. Hodder, MD

Richard A. Hodder, MD provided a declaration admitted as P. Ex. 31 and testified at hearing. Tr. 653. Based on Dr. Hodder's testimony (Tr. 663-71; P. Ex. 31), and his curriculum vitae (P. Ex. 30), I accept Dr. Hodder as well-qualified to render opinions related to long-term care and infectious disease medicine, including active TB and latent TB infection (Tr. 1107). *See* Fed. R. Evid. 702-704. A letter from Dr. Hodder to counsel for Petitioner was also admitted as evidence without objection as P. Ex. 29. He opined that the 2005 CDC guidelines and the Maryland guidelines from 2007, place the primary responsibility for ensuring the quality and completeness of TB services, including planning for the treatment and follow-up with contacts to someone with active TB, upon the county health department. P. Ex. 31 at 7. He testified that Petitioner's policies and procedures (P. Ex. 6) stress the role of the county health department and impose no requirement for either Petitioner's medical director or a resident's physician to take the lead to initiate investigation of contacts or order treatment of a resident with latent TB infection. He testified: "I know that when I was a long term Medical Director, I would not issue blanket TB prophylaxis orders without specific direction from the local public health authority." P. Ex. 31 at 8. This testimony is credible and significant because it shows that as a medical director, Dr.

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Hodder knew it was his responsibility to order treatment for latent TB infection, however, he only did so with specific direction from the local public health authority.

Dr. Hodder opined that the county health department seriously departed from CDC and Maryland guidelines in March and April 2015, by not taking immediate action to declare a significant public health emergency and to dispatch a professional team to Petitioner to provide on-site direction and follow-up every day. P. Ex. 31 at 9-10, 12. While I accept Dr. Hodder's opinion, the Montgomery County, Maryland health department is not subject to my jurisdiction and the conduct of the department is not on trial before me.

Dr. Hodder opined that someone from the county health department should have assessed the residents for treatment for latent TB infection, determined which residents should have started treatment, and either recommended or given orders for treatment. P. Ex. 31 at 13-15. Dr. Hodder does not reveal the basis for his opinion, which I read to be that the county health department should assume the responsibility to diagnose and treat residents. I have received no evidence that it is standard of care for a county health department to assume responsibility for the treatment of long-term care facility residents. He opined it is improbable that any recommendations for treatment were sent by the county health department to Petitioner. P. Ex. 31 at 15. This is not an opinion within Dr. Hodder's scope, rather it is a judgment I must make by weighing the evidence. I accept as fact that Dr. Hodder found or was given no recommenda-

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tions for treatment from the county health department, which is consistent with the fact that ADON Hayden denies receipt of recommendations and the county health department concedes it cannot find the recommendations sent to Petitioner by facsimile. I do not find that no recommendations were made, simply that no recommendations were actually received by Petitioner's staff.

Dr. Hodder expresses the expectation that the county health department would have provided close supervision and follow-up for treatment ordered for residents for latent TB infection. He found no evidence of follow-up by the county health department. P. Ex. 31 at 15. His opinion assumes that the county health department prescribed treatment, but there is no evidence to support that assumption. Rather, the evidence shows that the county health department sent treatment recommendations, not received by Petitioner, not that the county health department ordered a specific course of treatment and undertook to care for residents with latent TB infection, at least not until September 2016 (P. Exs. 26-27). Dr. Hodder points out that in September 2015, a county health department representative drew blood from staff members and eight residents. However, because the blood draw was unsuccessful for four residents, the county was to send a phlebotomist to attempt another blood draw. He states he understood the county did not complete the blood draw for the four residents who required a phlebotomist. P. Ex. 31 at 16. While it may be true that the county failed to draw blood for the four residents, the county health department is not subject to my jurisdiction. Furthermore, the fact that

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blood was not drawn for TB testing from four residents, does not address the other residents who were known to have latent TB infection and were not treated. He notes that quality assurance committee minutes from January 2016, show that Petitioner continued to wait for direction from the county health department. P. Ex. 31 at 16. He acknowledges that on November 5, 2015, the county health department asked whether Petitioner's medical director had started treatment for the residents with latent TB infection. ADON Hayden responded that no treatment had begun because the prior medical director had departed, and she asked for a meeting with the county health department representative, RN Fontana. P. Ex. 31 at 17; P. Ex. 18 at 4-6. He opines it is astonishing that ADON Hayden's response did not trigger an immediate response from the county health department. P. Ex. 31 at 17. Dr. Hodder overlooks the fact that ADON Hayden's response was not that treatment was not started because Petitioner was awaiting recommendations or orders from the county health department. The fact that the county health department did not immediately respond is questionable, but that department's failures are not subject to my review. The question from the county health department also did not provoke an immediate reaction by ADON Hayden or Petitioner's staff. Clearly the question of whether treatment had begun shows that the county health department had some expectation that treatment should have begun. Dr. Hodder observes that ADON Hayden advised RN Fontana that Petitioner had a new medical director and a meeting needed to be set to figure out a plan, but there was no response from the county. Dr. Hodder states he is unsure what further action ADON Hayden could have

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undertaken. P. Ex. 31 at 18. I note that there is also no evidence that ADON Hayden advised the new medical director of the county health department inquiry. I find no evidence that the new medical director attempted any follow-up with the county health department. Dr. Hodder stresses that Petitioner had a TB outbreak and that the county health department was astonishingly derelict in its failure to follow-up. P. Ex. 31 at 17. He does not comment upon the new medical director's failure to address the TB outbreak at Petitioner or suggest that the new medical director had a responsibility to take action to clarify the situation with the county health department so that treatment could be initiated expeditiously.

Dr. Hodder opines that Resident 1's symptoms, which manifested on June 4, 2016, could have been evidence of active TB, but the radiologist did not report a suspicion of active TB or any disease to the resident's physician. Resident 1's physician diagnosed acute bronchitis and ordered an antibiotic with improvement. Dr. Hodder points to no evidence that the resident's physician or the radiologist were informed that Resident 1 previously tested positive for latent TB infection. However, he opines that there was no reason why Petitioner's nurses, who were supposed to be monitoring Resident 1 for signs and symptoms of active TB, would question the treating physician's diagnoses. Dr. Hodder expressed no opinion regarding whether Petitioner's medical director had a duty to alert Resident 1's treating physician that she had a prior positive testing for latent TB infection and was at high risk to convert to active TB. P. Ex. 31 at 18-20. In August 2016, two months later, Resident 1 was diagnosed with active TB at which time the county

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health department again took action. All of Petitioner's residents and employees were again tested. Dr. Hodder states that the county health department then provided written orders for treatment of residents with latent TB infection. P. Ex. 31 at 20-21.

Dr. Hodder opined that the county health department failed in its mission by not notifying Petitioner immediately in March and April 2015, that two of its employees had active TB and by failing to provide on-site supervision at Petitioner's facility as long as necessary to ensure the TB outbreak did not spread and all responses were implemented. He notes he found no evidence that at any time in 2015, the county health department recommended or directed treatment of residents identified as having latent TB infection or conducted on-site confirmation of treatment with ongoing surveillance to ensure no residents presented with signs of active TB. P. Ex. 31 at 21-22. He opines that there was nothing more Petitioner's staff could have done, and ADON Hayden implemented Petitioner's infection control policy as well as she could absent direction and communication by the county department. P. Ex. 31 at 22. As already noted, I have no authority to review the county health department's performance of its duties.

On cross-examination, Dr. Hodder agreed that even if Petitioner did not receive treatment recommendations from the county health department for residents with latent TB infection, Petitioner was responsible to ensure that residents received treatment. Tr. 713-14. Dr. Hodder did not opine that treatment for latent TB infection was not required when not contraindicated.

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iii. More Than Minimal Harm

According to the CDC guidelines, the best scientific evidence presented to me and unrebutted, five percent of people with newly acquired latent TB infection progress to active TB within two years of exposure if there is no treatment. CMS Ex. 53 at 36. Petitioner tested its residents for TB between May and August 2015, and identified 19 to 20 residents with a positive test for TB but a negative chest x-ray, which is latent TB infection. PPFF ¶¶ 94, 99, 103-104, 116-20; CPFF ¶¶ 29-31, 33-35, 39; CMS Ex. 22 at 16-21; Tr. 1001-1022. One resident, Resident 4, was successfully treated for latent TB infection, per order of her physician, in connection with her preparation for a kidney transplant. P. Ex. 20 at 1-2; Tr. 1059-61; CMS Ex. 8 at 4, 21-22, 29, 40-45. Therefore, of the remaining 18 or 19 residents with latent TB, it was reasonable to anticipate that at least one of the residents with latent TB infection would convert to active TB within two years. In fact, no later than August 2016, just over one year after being identified as having latent TB infection, Resident 1 did convert to active TB.

According to CDR Morris, if not treated properly active TB can be fatal, and five percent of patients diagnosed in the United States each year with active TB are either dead when diagnosed or they die during treatment. CMS Ex. 42 at 2-3, 5. This opinion is not rebutted or challenged and is accepted as credible.

The risk for death associated with conversion to active TB is certainly a risk for more than minimal harm. The effects of treatment for active TB might also be more than minimal harm, but CMS presented no evidence of any adverse side effects from treatment

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for active TB or other risks associated with such treatment.

iv. Key Findings of Fact

In May and August 2015, Petitioner's staff and the county health department conducted two rounds of TB testing of residents who might have been exposed to an employee with active TB. Testing showed 19 or 20 residents with TB exposure and a list was provided to the county health department. Chest x-rays showed that none of the residents had active TB in 2015. The second round of testing was completed in August 2015, except for blood tests for four foreign born residents. PPFF ¶¶ 94, 99, 103-104, 116-20; CPFF ¶¶ 29-31, 33-35, 39; CMS Ex. 22 at 16-21; Tr. 1001-1022. There is no question that Petitioner's staff did a good job conducting the contact investigation and testing of residents in 2015, as attested to by RN Fontana. Tr. 578.

Blood tests were conducted by the county health department, and blood test results for only five residents were provided to Petitioner's staff. Tr. 1006-07.

There is no question that a positive TB test and negative chest x-ray shows that one has latent TB infection. CMS Exs. 30 at 10; 41 at 46; 42 at 3-4; 49 at 126-29; 53 at 4, 12. Petitioner concedes that a resident who had a positive test for TB and a negative chest x-ray should be treated at some time. P. Br. at 3.

Resident 4, one of the residents identified as having latent TB infection in 2015, was treated beginning about October or November 2015, pursuant to an order from a physician who evaluated her in preparation for a kidney transplant. PPFF ¶¶ 121-123; CPFF, 40; CMS Exs. 14 at 129; 28 at 2; P. Ex. 20 at 1-2.

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There is no dispute that the remaining 18 to 19 residents identified as having latent TB infection in 2015, including Resident 1, received no treatment for latent TB infection until September 2016. P. Reply at 16-17.

Petitioner's infection control policy, the part of that policy specifically applicable to TB, required that one identified with a positive TB test and a negative chest x-ray must be referred for medical evaluation for treatment. P. Ex. 6 at 6-7. Petitioner's policy did not say how quickly the medical evaluation needed to be requested. However, the un rebutted evidence shows that five percent of all persons with latent TB infection will convert to active TB infection, in many cases becoming infectious, within two years of exposure to TB. CMS Ex. 53 at 36. If not treated properly, active TB can be fatal, and five percent of patients diagnosed in the United States each year with active TB are either dead when diagnosed or they die during treatment. CMS Ex. 42 at 2-3, 5. Active TB in the throat or lungs can be infectious while active TB in other parts of the body are generally not. Active TB is most likely to be spread among people who spend time together every day. CMS Ex. 42 at 3. Residents and staff of congregate settings such as long-term care facilities are among those at highest risk for exposure and infection. CMS Ex. 41 at 7. The CDC stresses that the treatment of latent TB infection is essential to control and eliminate TB because it substantially reduces the risk that M. tuberculosis will progress to TB. CMS Ex. 41 at 55. Although Petitioner has suggested through its briefs that its medical directors and ADON Hayden had little or no experience handling a TB outbreak, Petitioner has never suggested that they did not know of the risk of conversion from latent TB

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to active TB and the risk that posed to all staff and residents for serious harm and possible death. Based on the known risks associated with TB, I infer that Petitioner's policy, which is not alleged to be defective, requires prompt action by Petitioner's staff for all steps required for handling a TB outbreak.

Regardless of how promptly Petitioner's staff may be expected to follow Petitioner's infection control policy, in this case, the 18 or 19 residents identified as having latent TB infection in 2015, were never referred to their primary care physicians for evaluation for treatment. Therefore, Petitioner's staff failed to follow an express requirement of Petitioner's infection control policy. Based on that failure, I find that Petitioner did not implement or maintain its infection control policy, which is the basis for noncompliance cited in this case.

There is no dispute that a decision was made to delay prophylactic treatment of the latent TB cases until after the second round of testing of Petitioner's residents was completed. Both the county health department and Petitioner's staff were aware of that decision. Tr. 585-87, 633-34, 1065; PPFF ¶ 111; CPFF ¶ 32. There is no evidence of any agreement between Petitioner's staff and the county health department or direction from the county health department as to how long treatment for latent TB infection could be delayed. There is also no evidence that the risk posed to residents due to the delay was actually assessed by either the county health department or Petitioner.¹⁷

¹⁷ CDR Morris opined that the agreement between ADON Hayden and the county health department to delay treating the group identified in May 2015 as requiring treatment until the August 2015 group was identified so that all were treated as a

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There is no evidence that any of the residents' physicians who should have been involved, Petitioner's medical directors, and the county health officer, were actually involved in decision-making regarding delayed treatment for latent TB infection.

b. Analysis

The parties have advanced multiple theories in their briefs and their arguments at hearing. Indeed, it is easy to lose focus in this case on the key facts and issues because the parties pursue many threads that have little or nothing to do with the actual deficiency citation.¹⁸ It is important to understand that the non-compliance alleged in the SOD and cited by CMS's initial determination defines and limits the facts and issues that require my de novo review.

The regulation Petitioner is alleged to have violated required:

cohort was acceptable. CMS Ex. 49 at 53-54. However, she also opined that the residents should have been diagnosed as having latent TB infections not later than September 2015. She opined that all residents assessed as having latent TB infection should have been offered and treated for latent TB infection absent a contraindication that should have been documented in their clinical records. CMS Ex. 42 at 12-15, 119. My understanding of her opinions was that a delay in treatment until around September 2015, would be acceptable, but after that the risk for conversion was too great a threat. I do not construe her opinions to be an endorsement of the delay in this case of nearly a year from September 2015 to August or September 2016.

¹⁸ Efforts have been made to discuss many theories and arguments in footnotes with some discussion to address their relative merit or lack thereof. Theories advanced which are not discussed in this decision were not overlooked but simply found to merit no discussion.

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The facility 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.

(a) Infection control program. The facility must establish an infection control program under which it—

(1) Investigates, controls, and prevents infections in the facility; (2) Decides what procedures, such as isolation, should be applied to an individual resident; and (3) Maintains a record of incidents and corrective actions related to infections.

(b) Preventing spread of infection.

(1) When the infection control program determines that a resident needs isolation to prevent the spread of infection, the facility must isolate the resident.

(2) The facility must prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease.

(3) The facility must require staff to wash their hands after each direct resident contact for which handwashing is indicated by accepted professional practice.

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42 C.F.R. § 483.65. The regulation requires that Petitioner establish and maintain an infection control policy. The Board in addressing 42 C.F.R. § 483.65 has held that the regulation requires that a facility do more than merely adopt an infection control policy, the regulation requires that the policy be implemented. *Golden Living Ctr. – Superior*, DAB No. 2768 at 7 (2017); *Heritage House of Marshall Health & Rehab. Ctr.*, DAB No. 2566 at 12 (2014); *The Windsor House*, DAB No. 1942 at 60 (2004); *Park Manor Nursing Home*, DAB No. 2005 at 60 (2005).

Surveyor Slade testified that she was the only surveyor for the complaint investigation at Petitioner on September 27, 28, and October 6, 2016. She testified that she drafted the allegation of noncompliance under Tag 441 in the SOD based on a violation of 42 C.F.R. § 483.65. The purpose of the survey was to investigate complaints related to a TB outbreak at Petitioner. She declared immediate jeopardy on October 6, 2016, and immediate jeopardy was abated that day. CMS Ex. 43 at 3-4. Surveyor Slade testified that she concluded Petitioner violated 42 C.F.R. § 483.65 because Petitioner failed to implement proper infection control measures after residents were exposed to active TB by two infected employees; Petitioner failed to follow-up with treatment and management of multiple residents identified as at risk for exposure who had latent TB infection; Petitioner failed to ensure that a diagnosis of latent TB infection and treatment decisions were documented in clinical records, and failed to ensure treatment for latent TB infection was provided as appropriate. CMS Ex. 43 at 4. In the case of Resident 1, latent TB infection progressed to active TB by about June 14, 2016, but Petitioner failed to

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provide treatment or isolation for Resident 1 from June 14, 2016 through August 2016 when she had to be hospitalized. CMS Ex. 43 at 4-5. Surveyor Slade opined that the regulatory violation posed a risk for more than minimal harm and immediate jeopardy. CMS Ex. 43 at 5. Surveyor Slade opined that the facility was obliged to notify treating physicians of positive TB test results so that the physicians could decide whether to treat or not. Tr. 312-13. I do not accept Surveyor Slade's opinion that Resident 1's latent TB infection progressed to active TB on June 14, 2016. Although Surveyor Slade is qualified as a surveyor, I have no evidence she is qualified to render such a diagnosis. CDR Morris' testimony that Resident 1 had symptoms consistent with active TB in June 2014, may be viewed to bolster Surveyor Slade's opinion. However, CDR Morris did not actually examine Resident 1 or review more than the limited records available to me in this case. Furthermore, CDR Morris did not render a diagnosis but only opined that Resident 1's symptoms were consistent with active TB. CMS Ex. 42 at 12, 14.

Surveyor Slade cited only four specific residents as examples under Tag F441 in the SOD—Residents 1, 5, 6, and 7. On my examination, Surveyor Slade testified that she examined the records of only five residents who had positive tests for TB. Resident 1 was one of the examples she examined. She testified that Resident 1's records included two positive TB test results and a negative chest x-ray from May and September 2015. She agreed the test results and x-ray are consistent with latent TB infection and that the interdisciplinary team should have had access to that

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information in Resident 1's clinical record. She testified that she saw no diagnosis of latent TB infection entered in the resident's records, no care plan, no physician note, and nothing on the resident's face sheet. Tr. 336-39; CMS Ex. 5.¹⁹ Petitioner conceded that while the results of TB testing were entered in resident charts, no diagnosis of latent TB infection was noted in resident clinical records because no physician from the county health department or the facility rendered such a diagnosis. Tr. 143-44. Petitioner agreed at hearing that there is no dispute that staff reported all positive TB test results in 2015 to the county health department, but Petitioner denies ever receiving a diagnosis or treatment orders for any resident with latent TB infection in 2015 or early 2016. Tr. 295-96.

A precise parsing of the actual allegations in the SOD of the basis for Surveyor Slade's determination of noncompliance is required because her allegations in testimony are both more extensive and more precise than the actual findings and conclusions of the noncompliance alleged in the SOD. Surveyor Slade alleges in the SOD that Petitioner was not in substantial compliance with the requirements of 42 C.F.R. § 483.65 for the following reasons:

Petitioner failed to ensure timely follow-up of the treatment and management of multiple residents identified as at risk for exposure to a serious infectious disease; and

¹⁹ Pages 2 through 4 of CMS Ex. 5 are surveyor notes, not part of Resident 1's clinical record.

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Petitioner failed to record in residents' clinical records the rationale for treatment or non-treatment for the potential exposure.

CMS Ex. 1 at 7. More specifically the first allegation is that Petitioner identified 19 to 20 residents who were exposed to TB, evidenced by the fact they had latent TB infection, i.e., a positive test for TB followed by a negative chest x-ray, but failed to provide treatment for the latent TB infection or monitoring for those for whom treatment was contraindicated or those who refused treatment. The second allegation is that Petitioner did not document why no treatment was provided to the residents with latent TB infection. Documentation is important to ensure treatment decisions are based on the best and most comprehensive information and to establish that quality care was delivered. Petitioner's infection control policies and procedures in evidence do not specifically establish or address documentation requirements, and there is no allegation that the policies and procedures were deficient for failure to establish documentation requirements. Therefore, failure to document is not a violation of Petitioner's infection control policy or 42 C.F.R. § 483.65. However, the absence of documentation means that there is little or no documentation that Petitioner's staff actually did what was required by Petitioner's policy and procedure, i.e., medical evaluation by primary care physicians to determine the best plan of care including treatment for latent TB infection, if not contraindicated, and monitoring. P. Ex. 6 at 6-7. I note that Petitioner has never actually asserted that primary care physicians conducted medical evaluations and made treatment decisions for any resident with latent TB infection other than Resident

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4. Therefore, one cannot expect to find documentation of referral for medical evaluation, medical evaluation, treatment orders, or engagement of a resident's interdisciplinary team in care planning for the treatment or monitoring of the residents with latent TB infection as required by 42 C.F.R. § 483.20(k)(2).²⁰ I conclude that Petitioner violated 42 C.F.R. § 483.65 for the reasons alleged by the surveyor in the SOD, and alternative theories of liability mentioned by CMS at hearing and in post-hearing briefing are not discussed in detail or considered in concluding Petitioner was non-compliant.

i. CMS's Prima Facie Case

Petitioner argues that CMS cannot make a prima facie showing in this case because CMS cannot show that the county health department sent and Petitioner received treatment recommendations for residents with latent TB infection in the fall of 2015. P. Reply at 2. There is credible evidence the county health department sent treatment recommendations to Petitioner's medical director. However, there is also credible evidence, sufficient to overcome any presumption of receipt, that the treatment recommendations were not received. My conclusion that Petitioner violated 42 C.F.R. § 483.65, does not turn on whether or not Petitioner ever received treatment recommendations from the county health department anyway.²¹

²⁰ The requirement for care planning moved to 42 C.F.R. § 483.21 effective November 28, 2016. 81 Fed. Reg. 68,688; 68,689; 68,737-43; 68,858.

²¹ Even if I found as fact that Petitioner's medical director did receive the recommendations for some of the residents with latent TB infection and failed to share them with other staff, it would not affect the outcome. Similarly, if Petitioner's staff did

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Surveyor Slade did not allege that Petitioner did not have the required infection control policy or that the policy was defective. CMS Ex. 1 at 6-15. CMS also does not allege Petitioner failed to have the required policy. Rather, it is alleged that Petitioner failed to maintain or implement its infection control program to prevent infection by treating and managing residents with latent TB infection and Petitioner failed to document a rationale for not treating residents with latent TB infection.

Pursuant to 42 C.F.R. § 483.65(a), Petitioner's infection control program must: (1) control and prevent infections in the facility; (2) require a decision on what procedures must be applied to an individual resident, and (3) result in a record of incidents and corrective actions related to infections. The requirements of 42 C.F.R. § 483.65(a) for Petitioner's policy to address and be implemented to control and prevent infections and require decisions related to procedures to be applied for individual residents are clearly placed in issue by the SOD in this case. CMS Ex. 1 at 7. The requirement of 42 C.F.R. § 483.65(a) to create a record of incidents and corrective actions, does not appear to be implicated in this case as it is not alleged that Petitioner's infection control nurse failed to create such records. Prevention of the spread of infection is ad-

receive the recommendations and simply failed to notify primary care physicians so that they could prescribe treatment, the outcome in this case would be no different. Thus, under either scenario, receipt or non-receipt of recommendations are facts that are really immaterial. *See* Fed. R. Evid. 401(b). Petitioner would be no less liable for failure to follow its infection control policy in either case.

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dressed by 42 C.F.R. § 483.65(b), which requires isolation of residents, prohibiting infected employees from contact with residents, and handwashing. There is no allegation in the SOD that Petitioner failed to prohibit infected staff from contact with residents or that there was a failure to require staff handwashing. Regarding isolation, if Resident 1 had active TB in June 2016, then clearly she should have been isolated and moved immediately under Petitioner's policy. P. Ex. 6 at 6. Resident 1 was not moved, however, until August 2016, when she was diagnosed as having active TB. I do not read the SOD as clearly alleging that Petitioner violated or failed to maintain its policy because Petitioner's staff failed to isolate and move Resident 1 in June 2016. CMS Ex. 1 at 7. Indeed, there is no contemporaneous evidence from June 2016, which shows that Resident 1 was actually diagnosed with active TB and Petitioner's staff should have known that it needed to comply with its infection control policy related to active TB. Accordingly, I do not conclude that Petitioner's failure to isolate Resident 1 in June 2016, was a failure to follow Petitioner's infection control policy.²²

I conclude that CDC and Maryland guidelines and the Maryland regulations establish the standard of care for latent TB infection in long-term care facility

²² I recognize that Surveyor Slade did allege that immediate jeopardy began on June 14, 2016, which happened to be when Resident 1 had signs and symptoms that may have been consistent with, and Surveyor Slade seems to have determined were consistent with, the onset of active TB, even in the absence of a physician's diagnosis. CMS Exs. 1 at 10- 11; 43 at 3-5. However, as discussed hereafter Petitioner has the burden to show that the declaration of immediate jeopardy was clearly erroneous, and Petitioner has failed to meet that burden.

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residents. The CDC stresses that treatment of latent TB infection is essential to control and eliminate TB. CMS Exs. 41 at 55; 53 at 60, 70. Nursing home residents are at higher risk for infection. CMS Exs. 30 at 9; 41 at 7, 29; 42 at 11; 53 at 17, 60. Residents are at highest risk for progression from latent TB infection to active TB infection during the first two years after exposure if there is no treatment. CMS Exs. 41 at 7; 42 at 3; 53 at 12, 36. The CDC recommends that people with latent TB infection be treated absent compelling contraindications. CMS Exs. 42 at 4, 6; 53 at 60, 70; P. Ex. 4 at 7. The CDC states that control of TB in nursing homes requires prompt detection and diagnosis, isolation of those who are infectious, and initiation of standard therapy. CMS Exs. 41 at 86; 53 at 60, 70. The CDC also states that treatment of latent TB infection can reduce the risk for death due to progression, i.e., conversion, to active TB. CMS Exs. 32 at 5-6, 33 at 6. The standard of care under CDC and Maryland guidelines and Maryland regulations is treatment of latent TB infection, unless contraindicated. CMS Exs. 30 at 8; 32 at 5-6; 33 at 6; 39 at 19; 41 at 55, 86; 53 at 17, 60, 70; P. Ex. 4 at 7. Petitioner concedes that a resident who had a positive test for TB and a negative chest x-ray should be treated at some time. P. Br. at 3. Preferred treatment for latent TB infection is isoniazid (INH) for six to nine months according to both the CDC and Maryland guidelines. CMS Exs. 30 at 18; 41 at 55, 86; 39 at 20-21, 28-30, 59. The Maryland guidelines recommend treating for latent TB infection to reduce the possibility of progression to active TB. CMS Ex. 39 at 19. Maryland specifies that either INH or rifampin should be used for treatment of latent TB infection. CMS Ex. 39 at 20-21, 28-30, 59.

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The Maryland regulations require that a nursing home assess all residents annually for signs and symptoms of TB. If any signs and symptoms are detected, a physician must then evaluate for TB in communicable form, and the county health department must be notified within 24 hours if active TB is suspected. The physician is required to coordinate the management of resident and resident's contacts with the county health officer. A nursing facility is required to assess and manage a resident with possible TB in accordance with CDC guidelines. CMS Ex. 38 at 17.

A portion of the Petitioner's infection control policy and procedures related to TB has been admitted to the record as P. Ex. 6. Petitioner's policy requires that when TB²³ is identified the health department is to be notified and the recommendations of the health department are to be followed; staff is to conduct an investigation to determine if any staff or residents have been exposed to TB; and the treatment needs of any residents exposed are to be determined. P. Ex. 6 at 1-2. Petitioner's TB screening procedures and post TB exposure procedures require skin testing for TB, except when blood testing is required. If a skin test is positive, a chest x-ray is to be ordered. If the chest x-ray is positive for TB, the resident is isolated and transferred to an appropriate facility as soon as possible. If the chest x-ray is negative, alternative diagnoses are to be considered and the resident is to be evaluated for chemoprophylaxis, i.e., treatment of the latent TB infection. P. Ex. 6 at 3-7. Petitioner's policy

²³ Petitioner's policy is potentially confusing because it is not clear when "TB" is used whether it is a reference to active TB, infectious TB, or latent TB infection.

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and procedures are not inconsistent with the standard of care defined by the CDC and Maryland guidelines.

There is no dispute that between May and September 2015, 19 to 20 of Petitioner's residents were identified as having latent TB infection. The evidence shows that Resident 4 received further medical evaluation in connection with her evaluation for a kidney transplant, and treatment for her latent TB infection was ordered by a physician related to her evaluation for the transplant with treatment administered by Petitioner's staff PPFF ¶¶ 121-123; CPFF ¶ 40; CMS Ex. 8 at 4, 21-22, 29, 38-45; CMS Exs. 14 at 129; 28 at 2; P. Ex. 20 at 1-2; Tr. 1059-61. There is no dispute that the remaining 17 to 18 residents received no treatment for latent TB infection until September 2016. Resident 1 did not receive treatment for latent TB infection but began treatment for active TB in August 2016. P. Reply at 16-17. There is no evidence that in 2015, Petitioner's staff informed the residents' treating physicians of the residents' positive skin tests and negative chest x-rays and requested medical evaluation of the residents by their physicians for treatment of latent TB infection, as required by Petitioner's policy and procedures. Therefore, Petitioner's staff did not comply with Petitioner's infection control policy related to TB. DON Odunubi testified that it was not Petitioner's practice to update care plans for residents identified with latent TB unless treatment was initiated; physicians who saw patients at Petitioner did not place a diagnosis of latent TB on residents' clinical records; and Petitioner's staff simply monitored annually for conversion from latent TB to active TB. Tr. 1086-88. DON Odunubi's testimony suggests that TB

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outbreaks were regularly dealt with at Petitioner, contrary to the representation of Petitioner throughout this case that its staff had little experience dealing with TB and therefore had to rely upon the county health department. I conclude that DON Odunubi's testimony is not credible and, even if it was, her testimony does not outweigh Petitioner's policy and procedure that requires medical evaluation for a treatment for a resident identified as having latent TB infection. There is no dispute that the residents with latent TB infection, other than Resident 4, were not evaluated for treatment by their primary care physicians in 2015 or early 2016.²⁴

I conclude that Petitioner's infection control program, specifically the policies and procedures related to TB, was not implemented by Petitioner's staff to

²⁴ CMS also argues that Petitioner's annual monitoring for signs and symptoms of active TB (P. Ex. 21) was inadequate for residents with latent TB infection. CMS Br. at 12-16. Petitioner's policy provides that if a resident has a positive test for TB but a negative chest x-ray, the resident is to be monitored at least annually for signs and symptoms of active TB. P. Ex. 6 at 4. While I agree with CMS that annual monitoring is probably not adequate based on the evidence in this case, Petitioner was not cited because its infection control policy was inadequate. CMS Ex. 1 at 5-15. Furthermore, partial records of only seven residents with latent TB infection were placed in evidence and it is not possible to determine how much monitoring was actually done or not done. Certainly, staff recorded signs and symptoms of Resident 1 in June and August 2016, that were consistent with active TB. CMS Ex. 5 at 2, 43, 46-48, 55-58, 61, 62-72. Therefore, staff was monitoring Resident 1 but simply failed to recognize and/or failed to advise the treating physician that Resident 1 may have had active TB in June and August 2016. However, staff's failure is more symptomatic of a lack of competency and inadequate training than a failure to implement Petitioner's infection control policy.

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prevent the development and spread of active TB. I conclude that, although Petitioner had the required policy, it was not maintained, i.e., implemented, as required by 42 C.F.R. § 483.65. Petitioner did not implement its policy to prevent the spread of TB infection by ensuring that residents identified as having latent TB infection were treated, unless contraindicated or refused, in accord with CDC and Maryland guidelines which establish the standard of care. Petitioner's staff failed to request the residents' primary care physicians or Petitioner's medical director evaluate the residents for appropriate treatment for latent TB infection. More than minimal harm was posed by the regulatory violation because as demonstrated by Resident 1, there was a risk for actual harm due to the conversion to active TB.²⁵ CMS Ex. 42 at 4-5, 13-14.

²⁵ CMS argues that Petitioner failed to ensure that Resident 1 received treatment for latent TB infection and suffered harm when she converted to active TB. CMS Br. at 11-12. CMS also argues that Petitioner failed to monitor Resident 1 for signs and symptoms of active TB to identify when she converted from latent to active TB; and Petitioner failed to timely diagnose and treat Resident 1's active TB. CMS Reply at 2. The argument CMS advances is really that Petitioner failed to deliver necessary care and services and or neglected Resident 1's care. Those charges are not before me and are not considered bases for imposing enforcement remedies in this case. Pursuant to 42 C.F.R. § 498.30, CMS had 12 months from the date of its January 31, 2017 notice of initial determination to reopen and revise that initial determination. CMS failed to reopen and revise before January 31, 2018, to add new citations of noncompliance or to change the period and amount of the CMP. CMS also argues Petitioner failed to isolate Resident 1 when she developed signs of active TB in June 2016. CMS Reply at 2, 6-8. There is no dispute that in June 2016, Petitioner's staff did not seem to recognize Resident 1's signs and symptoms were possibly consistent with active TB. Therefore, there was no evidence of

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Petitioner does not dispute that active TB is a contagious and life threatening disease. The potential for conversion to active TB as in the case of Resident 1, establishes that there was a risk for more than minimal harm and immediate jeopardy for all Petitioner residents, particularly those with latent TB infection.

ii. Petitioner's argument that the county health department did not do its duty and that Petitioner was waiting on treatment recommendations from county health officials is no defense.

Petitioner urges me to find that its staff did all that was required under state and federal law for various reasons discussed hereafter and that Petitioner did not violate 42 C.F.R. § 483.65 and remained in substantial compliance. P. Br. at 6. Petitioner argues that CMS failed to make a prima facie showing of a violation of 42 C.F.R. § 483.65, an argument I reject based on the preceding discussion. Petitioner also argues that it has rebutted the CMS prima facie case, an argument I address hereafter.

Surveyor Slade cited Petitioner for violating 42 C.F.R. § 483.65, not because Petitioner did not have an infection control policy but because Petitioner failed to follow, i.e., implement or maintain, its exist-

consideration of the need to isolate Resident 1 at that time and no violation of Petitioner's policy requiring isolation when there is suspected or confirmed TB. This failure does not reflect a failure to implement Petitioner's infection control policy but, rather, a failure to ensure that Petitioner's staff was adequately trained and competent to recognize the signs and symptoms of active TB.

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ing policy. The surveyor alleged noncompliance because Petitioner failed to ensure timely treatment and management of multiple residents identified as having latent TB infection and because Petitioner did not document in the residents' clinical records why no treatment occurred. CMS Ex. 1 at 7. Therefore, this case turns on the facts that Petitioner had an infection control policy that required evaluation for treatment for latent TB infection (treatment could be contraindicated or refused), but no residents identified with latent TB infection during testing in 2015 were referred for treatment to their primary care physicians or received treatment prior to September 2016, except Resident 4. Only Resident 4 received treatment administered by Petitioner's staff based on the order of an infectious disease doctor who evaluated her preparatory to kidney transplantation. The absence of documentation of a decision to treat or not treat for latent TB infection noted by the surveyor is important as it supports an inference that there was no follow-up, no treatment, no determination that treatment was contraindicated, and no refusal of treatment by an individual resident.

The clearest statement of a theory in this case is provided by Petitioner in its post-hearing brief. Petitioner's argument in response to the actual deficiency citation can be summarized by the following points: all witnesses agreed that treatment for residents with latent TB was necessary; the county health department agreed to provide recommendations for treatment for individual residents; there was an agreement to wait until after the second round of testing was completed in the fall 2015; the county health department never

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finished collecting blood from four residents for testing; and Petitioner never provided any treatment to those residents with latent TB infection in 2015, except Resident 4, because Petitioner never received recommendations from the county health department. P. Br. at 35; P. Reply at 16-17. Petitioner argues that its infection control policy and procedures, specifically that part related to TB, require notification of the county health department and following the county's guidance, which Petitioner argues is consistent with CDC and Maryland guidance. Petitioner argues it was waiting for county health department treatment recommendations of residents with latent TB infection identified in 2015, when in 2016 Resident 1 developed active TB. The gist of Petitioner's argument is that because it did not receive recommendations from the county health department it should have no liability for its failure to control the TB outbreaks in 2015 and 2016, and the harm caused. Petitioner does not acknowledge, to the detriment of Petitioner's credibility, that primary care physicians for each of the 18 or 19 residents infected with latent TB infection could have promptly evaluated their patients and ordered treatment, for cases in which treatment was not contraindicated or refused, using one of the two antibiotics authorized by the Maryland regulations. The example of Resident 4 proves that individual physicians can order treatment for latent TB infection and do so promptly after diagnosis. The evidence shows that not later than November 2015, ADON Hayden was aware that treatment for latent TB infection had been ordered for Resident 4 by one of her physicians.

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Petitioner challenges me to clearly delineate the respective responsibilities of the county health department and Petitioner related to the TB outbreak. Petitioner argues that CMS has never correctly described a SNF's responsibilities under 42 C.F.R. § 483.65, because CMS has not "defined or described the respective *legal* responsibilities" of a SNF and a county health department under controlling standards. P. Reply at 1-2 (emphasis in original), 8-16. Petitioner agrees that it has some obligation with respect to TB control under 42 C.F.R. § 483.65 and clarifies that it does not suggest that the county health department can take over a SNF's infection control program or treat residents. However, Petitioner argues that Petitioner's staff had little or no experience handling TB and for that reason Petitioner's policy directed that Petitioner's staff follow direction of the county health department. P. Reply at 15-16. Petitioner, however, argues the county health department did not do its job. Petitioner argues it did seek county guidance and complied with all county health department guidance and CMS has failed to show that Petitioner had any additional obligation under 42 C.F.R. § 483.65. P. Reply at 16.

Using Petitioner's summary of its theory of this case, it is relatively simple to illustrate the deficiency and respond to Petitioner's challenge. Petitioner's obligations to its residents are set forth in 42 C.F.R. pt. 483. Petitioner has the responsibility to deliver necessary care and services for its residents. 42 C.F.R. § 483.25.²⁶ One of the responsibilities established by

²⁶ The quality of care requirements of 42 C.F.R. § 483.25 were revised effective November 28, 2016, but the regulation number

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42 C.F.R. § 483.65 is that Petitioner “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.” TB is a disease. The county health department has responsibility to oversee the prevention and management of TB. The county health department has the responsibility under the Maryland guidelines to identify, promptly evaluate, and ensure an appropriate course of treatment is prescribed and completed for all people suspected of having TB. CMS Ex. 38 at 10. The Maryland regulations require that a health officer recommend appropriate treatment for latent TB infection. CMS Ex. 38 at 19. I accept based on undisputed evidence in this case that the county health department failed its duty because the county health department did not complete blood testing of four residents; failed to ensure that Petitioner received the county health department recommendations for treatment; and failed to ensure treatment was initiated in late 2015 or early 2016 for all residents identified as having latent TB infection.

However, the fact that the county health department did not promptly discharge its duties cannot be a defense for Petitioner’s failure to follow its infection control policy as required by 42 C.F.R. § 483.65. Dr. Passi, Petitioner’s medical director, Dr. Ajani, the successor medical director, and ADON Hayden, Petitioner’s infection control nurse, should have been thoroughly familiar with the respective responsibilities

and the requirement to ensure that residents received necessary care and services were unchanged. 81 Fed. Reg. 68,688; 68,745.

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and their relationship with the county health department to ensure Petitioner's residents were protected to the maximum extent during the TB outbreak. Clearly residents were not protected as reflected by the conversion of Resident 1 from latent TB infection to active TB. Petitioner's policy requires medical evaluation and determination of treatment for TB, including latent TB infection. P. Ex. 6 at 6-7. Petitioner failed to follow its policy. Contrary to Petitioner's argument, the alleged noncompliance in this case is not based on Petitioner's failure to follow specific directions from the county health department, or that Petitioner failed a duty to initiate treatment for individual residents who had latent TB infection. P. Br. at 37. The alleged noncompliance is that Petitioner failed to implement or maintain its infection control policy. Petitioner's policy requires that if TB exposure occurs in Petitioner's facility, as happened in early 2015, the health department was to be notified and its recommendations for investigation and follow-up were to be followed; an investigation was to be done to identify if any residents or staff were exposed; and if a TB test was positive, a chest x-ray was to be done, and if the chest x-ray was negative, medical evaluation was to be obtained for treatment. P. Ex. 6 at 6-7.

Petitioner argues that the county health department was not demonstrating any sense of urgency, and it was not for ADON Hayden or any member of Petitioner's staff to second guess the county health department. P. Br. at 37. Petitioner argues that the county health department's actions "at best were lackadaisical, if not negligent or worse." P. Br. at 37. Petitioner points out it took the county months to inform Petitioner that Petitioner had two infected employees;

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the county agreed to delaying treatment for at least six months after TB was identified; the county delayed blood tests and never finished some tests; and in January 2016, RN Fontana was still proposing a meeting to discuss how to proceed. P. Br. at 37-38. Petitioner asserts that no one involved in the investigation of the TB outbreak at Petitioner in 2015, expressed any urgency about beginning treatment for latent TB infection until nearly a year and a half after the outbreak was detected. P. Reply at 35. Petitioner asserts it is not clear how Petitioner's staff could discern from 42 C.F.R. § 483.65 or their experience that the county health department was botching the case. P. Br. at 38. Petitioner's assertions miss the point that it is Petitioner's compliance with its own infection control policy that is at issue.

Petitioner should have a much larger concern for the welfare of its residents than demonstrated by counsel's argument. Even if I accept as true that the county health department was dilatory, Petitioner provides no reasoned and supported argument that it should be relieved of the responsibilities to its residents it undertook when enrolling in Medicare. While the county had a duty under the Maryland regulations to recommend treatment for those residents with latent TB infection, Petitioner should have been concerned with ensuring that none of the residents converted to active TB, exposing all staff and residents to TB and the need for treatment for latent TB infection or, much worse, active TB and possible death. Petitioner's medical directors were obviously not particularly engaged or they would have been calling the state health department demanding action and meeting with all the primary care physicians to ensure that

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they did the medical evaluation and initiated prophylaxis consistent with Petitioner's policy. Nothing in the Maryland regulations or Maryland and CDC guidance suggests that the county health department may interfere with a primary care physician prescribing treatment for his or her patient, consistent with the two treatment modalities for latent TB infection specified in the Maryland regulation. Furthermore, Resident 4's case should have triggered action by Petitioner's medical director and ADON Hayden, as Resident 4's case provided a clear example that a private physician ordered treatment for his or her patient.

The Maryland guidelines specify that either isoniazid (INH) or rifampin is used for treatment of latent TB infection for six to nine months depending on the treatment regime. CMS Ex. 39 at 20-21, 28-30, 59. Therefore, even absent a specific recommendation, Petitioner could have anticipated that the recommendation would be one antibiotic or the other. Further, Petitioner could have provided the Maryland guidelines to the residents' treating physicians and then relied upon those physicians to issue appropriate orders for treatment. The Maryland guidelines specify that a private provider undertaking to treat one with TB is undertaking a public health function that includes prescribing an appropriate treatment regime and ensuring adherence to that regime until treatment is completed. CMS Ex. 39 at 10. Therefore, the Maryland guidelines specifically provide for a private provider ordering and treating one with TB and impose the obligation to ensure that treatment is completed. Dr. Passi or any of the other primary care physicians of the residents with latent TB infection could have ordered treatment for their residents within the scope

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of the Maryland guidelines. The Maryland guidelines recognize that residents of SNFs and NFs are at risk for infection and the recently infected are at risk for conversion from latent TB to active TB. The guidelines specify that a decision to test for TB is a decision to treat, including recent contacts with TB infection. CMS Ex. 39 at 12-14. Treatment should be targeted to high-risk groups including those recently infected and those in SNFs. CMS Ex. 39 at 19. The testimony of both CDR Morris and Dr. Hodder is consistent with the Maryland guidelines.

Petitioner argues that only the county health department had the resources to do the blood testing (QuantiFERON™) necessary for some staff and residents who were foreign born. The county health department drew blood from 31 residents on about May 27, 2015, and from another four residents in August 2015, and never drew blood for testing from four residents who required special skills to accomplish the blood draw. The county only provided Petitioner test results for five residents, three positive and two negative. P. Reply at 19-20; Tr. 572-75, 1006-07. If ADON Hayden or Petitioner's medical director believed that there were still residents who needed to have a blood test or that the county had not yet returned all of the test results to the facility, Petitioner's responsibility to its residents required follow-up with the county about those concerns. Petitioner did not follow-up or advocate in the best interests of its residents. Petitioner's attempts to shift blame to the county once again are therefore unpersuasive, particularly given that Petitioner knew it already had multiple residents

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with latent TB infection who required medical evaluation and orders for treatment under Petitioner's infection control policy.

Petitioner concedes:

It seems obvious that in any TB outbreak it is necessary for *someone* to take the lead in what plainly is a fairly complicated process, to give direction, and to follow up to assure that all necessary interventions have been completed.

P. Reply at 35 (emphasis in original). Petitioner argues that it is not clear at what point Petitioner's staff should have complained to the county health department or sought interventions by higher state authority. Petitioner states that its expert, Dr. Hodder, was clear that he would have been more aggressive under the circumstances. Petitioner asserts there is nothing in the regulations that shifts responsibility for handling a TB outbreak to Petitioner's staff or medical director. P. Reply at 35-36. Petitioner overlooks, however, its responsibilities under 42 C.F.R. § 483.25 to ensure its residents receive necessary care and services. Petitioner also overlooks its own policy, which places upon Petitioner's staff the responsibility to ensure medical evaluations for treatment are accomplished for those with latent TB infection. P. Ex. 6 at 6-7. Petitioner asserts that it was not unreasonable for ADON Hayden to continue to wait on the county health department even after January 2016, because there was an agreement to delay treatment for latent TB infection until after the second round of testing was done. In fact, as Petitioner represents, the county health department expressed no urgency about treatment even as of January 2016. P. Reply at 36-37.

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However, again Petitioner ignores its independent obligation to its residents to ensure they received necessary care and services as required by 42 C.F.R. § 483.25, in this case treatment for latent TB infection to prevent conversion of even one resident to active TB. The fact the county was not fulfilling its duty is no excuse for Petitioner's failure to fulfill its duty to its residents. In this case, Petitioner's own policy required Petitioner to ensure that medical evaluation for treatment of latent TB infection was done, and Petitioner failed to follow that policy, which is the basis for the deficiency citation.

Regarding Resident 1, Petitioner speculates that the resident's physician may not have treated Resident 1 differently if she had known that the resident had latent TB infection. P. Reply at 27-28. Petitioner did not call Resident 1's physician as a witness and speculation is no substitute for evidence. Whether or not Resident 1 had active TB as early as June 2016, is speculative and cannot be determined definitively on the present record. Although CDR Morris testified Resident 1 had classic signs of TB in June 2016, she did not examine the resident and I do not give her testimony greater weight than the medical evidence reflecting Resident 1's diagnoses by her treating physician at the time. However, the evidence does show that Resident 1 was identified as having latent TB infection in 2015, she was provided no treatment for latent TB infection, and as a result she developed active TB no later than August 2016.

The testimony of DON Odunubi and ADON Hayden reflects a fundamental misunderstanding of CDC and Maryland guidance. DON Odunubi testified that a

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positive skin test and negative chest x-ray did not result in a diagnosis of latent TB infection being placed on a resident's clinical records, or trigger a care plan revision unless treatment was initiated. Tr. 107 5-77. She testified that Petitioner's staff simply monitored for signs and symptoms that a resident had active TB. Tr. 1086-88. However, she ultimately agreed on cross-examination that residents with latent TB infection ought to be treated. Tr. 1094. ADON Hayden testified that she was not concerned about waiting for the county health department to make treatment recommendations or issue orders because latent TB infection is not infectious and Petitioner continued to do symptom surveillance. Tr. 1067-68. ADON Hayden testified that it was regular practice for Petitioner's staff to note in a resident's clinical record, specifically nursing notes, signs and symptoms the resident may have been experiencing, including any respiratory or lung symptoms. Tr. 1029-31. However, she testified that a positive TB test, which is certainly a sign or symptom, would have been noted on a resident's immunization status, not on the face sheet that is sent with a resident when transferred. She did not believe any diagnosis of latent TB infection was placed on a resident's face sheet. Tr. 1034-35. Both nurses, despite their years of experience in nursing, failed to recognize that there was a risk for a resident with latent TB infection, i.e., a positive TB test and negative chest x-ray, to convert to active TB and that treatment, not merely annual observation, was necessary to prevent conversion and exposure of other residents or staff to active TB. They failed to recognize that under Petitioner's infection control policy related to TB (P. Ex. 6 at 6-7) a medical evaluation needed to be obtained to determine whether treatment was contraindicated,

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and if not, treatment should be initiated, absent a refusal.

Petitioner argues that the survey should be rejected because Surveyor Slade worked for the same state agency as RN Townsend and RN Fontana. Petitioner reasons that there was a conflict of interest that raises a significant issue of the credibility of Surveyor Slade. P. Br. at 6-7 n.6, 36; P. Reply at 4 n.1. Even if Petitioner has identified a conflict of interest, this decision is not based on Surveyor Slade's testimony and observations in the SOD. My review is de novo and my decision is amply supported based on the testimony of the other witnesses, the documents other than the SOD, and the undisputed facts. Petitioner concedes that the Board has previously found that defects in the survey process are immaterial where there is an otherwise appropriate basis for finding noncompliance. P. Reply at 4 n.1.

I conclude that Petitioner has failed to rebut the CMS prima facie case or to establish an affirmative defense.

5. Petitioner failed to meet its burden to show that the declaration of immediate jeopardy related to the noncompliance under Tag F441 was clearly erroneous or that immediate jeopardy was abated before October 5, 2016.

Surveyor Slade concluded that the violation of 42 C.F.R. § 483.65 posed immediate jeopardy to resident health and safety from June 14, 2016, through October 5, 2016. Petitioner argues that there was no violation of 42 C.F.R. § 483.65 and no immediate jeopardy. P. Reply at 38.

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The CMS determination of immediate jeopardy must be upheld, unless Petitioner shows the declaration of immediate jeopardy to be clearly erroneous. 42 C.F.R. § 498.60(c)(2). CMS's determination of immediate jeopardy is presumed to be correct, and Petitioner has a heavy burden to demonstrate clear error in that determination. *Yakima Valley Sch.*, DAB No. 2422 at 8-9 (2011); *Cal Turner Extended Care Pavilion*, DAB No. 2384 at 14 (2011); *Brian Ctr. Health and Rehab./Goldsboro*, DAB No. 2336 at 9 (2010) (citing *Barbourville Nursing Home*, DAB No. 1962 at 11 (2005), *aff'd*, *Barbourville Nursing Home v. U.S. Dep't of Health & Human Svcs.*, 174 F. App'x 932 (6th Cir. 2006)); *Maysville Nursing and Rehab. Facility*, DAB No. 2317 at 11 (2010); *Liberty Commons Nursing & Rehab. Ctr.-Johnston*, DAB No. 2031 at 18-19 (2006), *aff'd*, *Liberty Commons Nursing & Rehab. Ctr.-Johnson v. Leavitt*, 241 F. App'x 76 (4th Cir. 2007). "Once CMS presents evidence supporting a finding of non-compliance, CMS does not need to offer evidence to support its determination that the noncompliance constitutes immediate jeopardy, rather, the burden is on the facility to show that that determination is clearly erroneous." *Cal Turner*, DAB No. 2384 at 14-15 (citing *Liberty Commons Nursing & Rehab. Ctr.-Johnston*, 241 F. App'x 76 at 3-4).

"Immediate jeopardy" under the regulations refers to 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, 489.3 (emphasis in original). In the context of survey, certification, and enforcement related to SNFs and NFs under the regulations, a conclusion

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by the state agency and CMS that noncompliance with program participation requirements poses immediate jeopardy to the facility residents, triggers specific regulatory provisions that require enhanced enforcement remedies, including authority for CMS to impose a larger CMP than may be imposed when there is no declaration of immediate jeopardy. 42 C.F.R. §§ 488.408(e), 488.438(a)(1)(i), (c), and (d). The regulations also require termination of the facility's provider agreement on an expedited basis or the removal of the immediate jeopardy through appointment of temporary management. 42 C.F.R. §§ 488.410, 488.440(g), 488.456, 489.53(d)(2)(B)(ii).

Pursuant to 42 C.F.R. § 498.3(d)(10), a finding by CMS that deficiencies pose immediate jeopardy to the health or safety of a facility's residents is not an initial determination that triggers a right to request a hearing by an ALJ or that is subject to review. Rather, a finding of noncompliance that results in the imposition of an enforcement remedy, except the remedy of monitoring by the state, does trigger a right to request a hearing and is subject to review. 42 C.F.R. §§ 488.408(g); 498.3(b)(8) and (13). Furthermore, the level of noncompliance, i.e., scope and severity, is subject to review only if a successful challenge would: (1) affect the amount of CMP that may be imposed, i.e., the higher range of CMP authorized for immediate jeopardy; or (2) affect a finding of substandard quality of care that rendered the facility ineligible to conduct a NATCEP. 42 C.F.R. § 498.3(b)(14) and (16). Pursuant to 42 C.F.R. § 498.60(c)(2), in reviewing a CMP, the ALJ must uphold the CMS determination of the level of noncompliance (i.e., the scope and severity),

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unless it is clearly erroneous. The phrase “clearly erroneous” is not defined by the Secretary.

Many appellate panels of the Board have addressed “immediate jeopardy.”²⁷ In *Mississippi Care Ctr. of Greenville*, DAB No. 2450 at 15 (2012), the Board commented:

CMS’s determination that a deficiency constitutes immediate jeopardy must be upheld unless the facility is able to prove that the determination is clearly erroneous. 42 C.F.R. § 498.60(c)(2); *Woodstock Care Center*. The “clearly erroneous” standard means that CMS’s immediate jeopardy determination is presumed to be correct, and the burden of proving the determination clearly erroneous is a heavy one. *See, e.g., Maysville Nursing & Rehabilitation Facility*, DAB No. 2317 at 11 (2010); *Liberty Commons Nursing and Rehab Center-Johnston*, DAB No. 2031 at 18 (2006), *aff’d*, *Liberty Commons Nursing and Rehab Ctr.-Johnston v. Leavitt*, 241 F. App’x 76 (4th Cir. 2007). When CMS issued the nursing facility survey, certification, and enforcement regulations, it acknowledged that “distinctions between different levels of non-

²⁷ Decisions often cited include: *Lakeport Skilled Nursing Ctr.*, DAB No. 2435 at 6 (2012); *Liberty Health & Rehab. of Indianola, LLC*, DAB No. 2434 at 13, 18-19 (2011); *Yakima Valley Sch.*, DAB No. 2422 at 8; *Lutheran Home at Trinity Oaks*, DAB No. 2111 (2007); *Daughters of Miriam Ctr.*, DAB No. 2067; *Britt-haven of Havelock*, DAB No. 2078 (2007); *Koester Pavilion*, DAB No. 1750; *Woodstock Care Ctr.*, DAB No. 1726.

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compliance . . . do not represent mathematical judgments for which there are clear or objectively measured boundaries.” 59 Fed. Reg. 56,116, 56,179 (Nov. 10, 1994). “This inherent imprecision is precisely why CMS’s immediate jeopardy determination, a matter of professional judgment and expertise, is entitled to deference.” *Daughters of Miriam Center*, DAB No. 2067, at 15 (2007).

The Board’s statement that the CMS immediate jeopardy determination is entitled to deference is subject to being misunderstood to limit ALJ and Board review of immediate jeopardy beyond what was intended by the drafters of the regulations. In the notice of final rulemaking on November 10, 1994, the drafters of 42 C.F.R. § 498.60(c)(2), discussing the merits of the reviewability of deficiency citations, selection of remedy, and scope and severity, commented:

We believe that a provider’s burden of upsetting survey findings relating to the level of noncompliance should be high, however. As we indicated in the proposed rule, distinctions between different levels of noncompliance, whether measured in terms of their frequency or seriousness, do not represent mathematical judgments for which there are clear or objectively measured boundaries. Identifying failures in a facility’s obligation to provide the kind of high quality care required by the Act and the implementing regulations most often reflect judgments that will reflect a range of noncompliant behavior. Thus, in civil money

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penalty cases, whether deficiencies pose immediate jeopardy, or are widespread and cause actual harm that is not immediate jeopardy, or are widespread and have a potential for more than minimal harm that is not immediate jeopardy does not reflect that a precise point of noncompliance has occurred, but rather that a range of noncompliance has occurred which may vary from facility to facility. While we understand the desire of those who seek the greatest possible consistency in survey findings, an objective that we share, the answer does not lie in designing yardsticks of compliance that can be reduced to rigid and objectively calculated numbers. Survey team members and their supervisors ought to have some degree of flexibility, and deference, in applying their expertise in working with these less than perfectly precise concepts. **For these reasons, we have revised the regulations to require an administrative law judge or appellate administrative review authority to uphold State or HCFA findings on the seriousness of facility deficiencies in civil money penalty cases unless they are clearly erroneous.**

59 Fed. Reg. at 56, 116, 56,179 (Nov. 10, 1994) (emphasis added). It is clear from this regulatory history that the drafters of 42 C.F.R. § 498.60(c)(2) ensured that the state agency or CMS determination that there was immediate jeopardy would receive deferential consideration, by adopting the clearly erroneous

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standard of review. Thus, caution must be exercised to ensure that the Board's decision in *Mississippi Care Ctr. of Greenville*; *Daughters of Miriam Ctr.*, and other decisions that have mentioned deference relative to immediate jeopardy not be read to require deference for the determination that there was immediate jeopardy beyond that imposed by adoption of the clearly erroneous standard. Giving deference or requiring that the immediate jeopardy determination be given deference in addition to applying the "clearly erroneous standard" would be contrary to the intent of the drafters of the regulation; would significantly limit the review of the determination by an ALJ and the Board; and would impermissibly deny an affected party the due process right to review intended by the drafters of the regulation.

In the foregoing quotation from *Mississippi Care Ctr. of Greenville*, that panel of the Board stated that the clearly erroneous standard means that "the immediate jeopardy determination is presumed to be correct, and the burden of proving the determination clearly erroneous is a heavy one." *Id.* at 15. Similar formulations have been used in other Board decisions when referring to the "clearly erroneous standard." However, the Board's characterization of the "clearly erroneous standard" in *Mississippi Care Ctr.* and other cases does not define the standard. The "clearly-erroneous standard" is described in Black's Law Dictionary as a standard of appellate review applied in judging the trial court's treatment of factual issues, under which a factual determination is upheld unless the appellate court has the firm conviction that an error was committed. *Black's Law Dictionary* 269 (8th ed. 2004). The Supreme Court has addressed the

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“clearly erroneous standard” in the context of the Administrative Procedures Act (APA). The Court described the preponderance of the evidence standard, the most common standard, as requiring that the trier-of-fact believe that the existence of a fact is more probable than not before finding in favor of the party that had the burden to persuade the judge of the fact’s existence. *In re Winship*, 397 U.S. 358, 371-72 (1970); *Concrete Pipe & Prods. of California, Inc. v. Constr. Laborers*, 508 U.S. 602,622 (1993). The “substantial evidence” standard considers whether a reasonable mind might accept a particular evidentiary record as adequate to support a conclusion. *Consolidated Edison*, 305 U.S. 197,229 (1938); *Dickinson v. Zurko*, 527 U.S. 150, 162 (1999). Under the “clearly erroneous” standard, a finding is clearly erroneous even though there may be some evidence to support it if, based on all the evidence, the reviewing judge or authority has a definite and firm conviction that an error has been committed. *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 395 (1948); *Dickinson*, 527 U.S. at 162; *Concrete Pipe*, 508 U.S. at 622. The clearly erroneous standard has been characterized by the Court as being stricter than the substantial evidence test and significantly deferential. The Court stressed in discussing the clearly erroneous standard the importance of not simply rubber-stamping agency fact-finding. The Court also commented that the APA requires meaningful review.²⁸ *Dickinson*, 527 U.S. at 162 (citations omitted); *Concrete Pipe*, 508 U.S. at 622-23.

²⁸ The Board’s characterization of the clearly erroneous standard as being highly deferential to the fact-finding by the state agency surveyor and CMS, and even triggering a rebuttal presumption, is entirely consistent with the Supreme Court’s

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Various panels of the Board have recognized other principles applicable to the review of the immediate jeopardy issue. A finding of immediate jeopardy does not require a finding of actual harm, only a likelihood of serious harm. *Dumas Nursing and Rehab., L.P.*, DAB No. 2347 at 19 (citing *Life Care Ctr. of Tullahoma*, DAB No. 2304 at 58 (2010), *aff'd*, *Life Care Ctr. of Tullahoma v. Sec'y of U.S. Dep't of Health & Human Servs.*, 453 F. App'x 610 (6th Cir. 2011)). The definition of immediate jeopardy at 42 C.F.R. § 488.301, does not define “likelihood” or establish any temporal parameters for potential harm. *Agape Rehab. of Rock Hill*, DAB No. 2411 at 18-19 (2011). The duration of the period of immediate jeopardy is also subject to the clearly erroneous standard. *Brian Ctr. Health and Rehab./Goldsboro*, DAB No. 2336 at 7-8. There is a difference between “likelihood” as required by the definition of immediate jeopardy and a mere potential. The synonym for likely is probable, which suggests a greater degree of probability that an event will occur than suggested by such terms as possible or potential. *Daughters of Miriam Ctr.*, DAB No. 2067 at 10. Jeopardy generally means danger, hazard, or peril. The focus of the immediate jeopardy determination is how imminent the danger appears and how serious the potential consequences. *Woodstock Care Ctr.*, DAB No. 1726.

characterization of the standard. However, the Court’s cautions about ensuring meaningful review rather than rubber-stamping agency decisions shows it is important for the ALJ and the Board not to be tempted to simply defer to the surveyor, the state agency, or CMS on the immediate jeopardy issue.

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What is the meaning of serious injury, harm, or impairment as used in the definition of immediate jeopardy found in 42 C.F.R. § 488.301? How does serious injury, harm, or impairment compare with “actual harm?” On the first question the Board recognized in *Yakima Valley Sch.*, DAB No. 2422 at 8, that the regulations do not define or explain the meaning of the term “serious” as used in the definition of immediate jeopardy.²⁹ The Board suggested that the definitions may be unimportant because the Board has held that, under the clearly erroneous standard, once the state agency or CMS declares immediate jeopardy there is a presumption that the actual or threatened harm was serious and the facility can only rebut the presumption of immediate jeopardy by showing that the harm or threatened harm meets no reasonable definition of the term “serious.” *Id.* (citing *Daughters of Miriam Ctr.*, DAB No. 2067 at 9). In *Daughters of Miriam Ctr.*, the Board discussed that the ALJ attempted to define “serious,” finding meanings such as dangerous, grave, grievous, or life-threatening. The Board notes

²⁹ Appendix Q of the SOM in effect at the time of the survey in this case, also failed to provide surveyors a working definition of the term “serious” that they can use to determine whether harm, injury, or impairment is serious when deciding whether or not to declare immediate jeopardy. The Act does not define the phrase “immediately jeopardize” and does not introduce the concept of serious harm, injury, or impairment as the basis for finding immediate jeopardy. Thus, one is not in error concluding that absent a definition of the term “serious” in the Act, the regulations, the SOM, or decisions of the Board, it is essentially up to individual surveyors, and whatever unpublished guidance they receive from their superiors or CMS officials, to exercise their individual discretion and judgment to decide that there was immediate jeopardy, which subjects a facility to the maximum imposable CMPs.

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that the ALJ stated that serious harm is outside the ordinary, requiring extraordinary care, or having lasting consequences. The Board further noted that the ALJ stated that a serious injury may require hospitalization, or result in long-term impairment, or cause severe pain, as opposed to harm, injury, or impairment that is temporary, easily reversible with ordinary care, does not cause a period of incapacitation, heals without special medical intervention, or does not cause severe pain. The Board did not endorse or adopt the ALJ's definitional exercise but concluded that it was simply unnecessary in the context of that case. The Board reasoned, as already noted, that the facility bore the burden to rebut the presumption by showing that the actual or threatened harm met no reasonable definition of serious. *Daughters of Miriam Ctr.*, DAB No. 2067 at 9-10.

Applying the clearly erroneous standard to the record before me related to the noncompliance I have found based on the violations of 42 C.F.R. § 483.65, I have no definite and firm conviction that an error has been committed. I conclude that Petitioner has failed to show that the declaration of immediate jeopardy for the deficiency under 42 C.F.R. § 483.65 was clearly erroneous.

I have concluded that Petitioner violated 42 C.F.R. § 483.65. The violation posed a risk for more than minimal harm to Petitioner's residents due to the risk associated with exposure to TB. I have also found and concluded that Resident 1 suffered actual harm because she did not receive treatment for latent TB infection and converted to active TB, which adversely affected her. Petitioner challenges the determination that immediate jeopardy was posed for Petitioner's

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residents based on its violation of 42 C.F.R. § 483.65. The gist of Petitioner's argument is there was no violation, no noncompliance, and no immediate jeopardy. I conclude based on the evidence of record that Petitioner has not met its burden under 42 C.F.R. § 498.60(c)(2) and shown that the declaration of immediate jeopardy was clearly erroneous, including the alleged duration.

Petitioner knew in August and September of 2015, that it had at least 18 to 19 residents with positive TB tests and negative chest x-rays, indicating that those residents had latent TB infection. The standard of care, according to the CDC (CMS Exs. 41 at 55; 53 at 17, 60, 70; P. Ex. 4 at 7), the State of Maryland (CMS Exs. 30 at 8; 39 at 12-14, 19, 20-21, 28-30, 59), CDR Morris (CMS Ex. 49 at 131), and Dr. Hodder (P. Ex. 31 at 13-15; Tr. 713-14), is treatment of latent TB infection to avoid conversion to active (infectious) TB, except when treatment is contraindicated or refused. According to the CDC, approximately five percent of people with newly acquired latent TB infection progress to TB within two years of exposure if there is no intervention. CMS Ex. 53 at 36. Approximately 5 to 10 percent of people with latent TB infection who are not treated will develop TB during their lifetimes. CMS Exs. 30 at 7; 41 at 6; CMS Ex. 42 at 3. If not treated properly, active TB can be fatal, and five percent of patients diagnosed in the United States each year with active TB are either dead when diagnosed or they die during treatment. CMS Ex. 42 at 2-3, 5. Therefore, untreated latent TB infection poses a risk for conversion to active TB infection and death. The conversion of even one resident to active TB, in this case Resident 1, can occur at any time. CMS Ex. 42

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at 15. Residents and staff of congregate settings such as long-term care facilities are among those at highest risk for exposure and infection. CMS Ex. 41 at 7. Active TB is most likely to be spread among people who spend time together every day. CMS Ex. 42 at 3. The CDC stresses that the treatment of latent TB infection is essential to control and eliminate TB because it substantially reduces the risk that the bacterium, *M. tuberculosis*, will progress to TB. CMS Ex. 41 at 55. Based on the unrebutted scientific evidence, with 18 to 19 residents with latent TB infection known to Petitioner in August or September 2015, Petitioner should have known that without treatment at least one of those residents was a ticking TB time-bomb that could go off at any time exposing even more residents and staff to TB. However, Petitioner did nothing to protect its residents choosing to wait on, using Petitioner's terms, the lackadaisical or neglectful county health department. Based on the undisputed risks for serious harm or death secondary to a conversion to infectious TB posed by even one resident in a long-term care environment, I would have no trouble concluding immediate jeopardy existed beginning no later than August 2015. The fact that there was an agreement to delay treatment for latent TB infection for the convenience of either the county health department or Petitioner's staff can be no excuse for Petitioner's failure to ensure there was prompt action to protect its residents. CDR Morris's opinion that the delay was acceptable (CMS Ex. 49 at 53-54), is not acceptable except from the perspective of the scientist or clinician who might find it convenient to treat multiple residents as a cohort. CDR Morris certainly did not suggest that there was a smaller probability of a

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conversion to active TB from latent TB infection during the first few weeks or months of exposure or provide any other basis for her opinion that waiting was acceptable other than for convenience.

CMS determined that immediate jeopardy began June 14, 2016.³⁰ I conclude that immediate jeopardy existed no later than June 14, 2016. I will not disturb CMS's exercise of discretion. CMS concluded that immediate jeopardy ended October 5, 2016. CMS Ex. 20 at 1-2. Petitioner has not shown that the declaration or duration of immediate jeopardy was clearly erroneous.

³⁰ The CMS initial determination issued January 31, 2017, included the determination that immediate jeopardy started on June 14, 2016. CMS Ex. 20 at 2. At hearing, counsel for CMS argued that June 14 was a typographical error and the inception of immediate jeopardy should have been June 4, 2016. Tr. 56-57, 62. CMS argued that on de novo review I should find that the evidence supported an inception of immediate jeopardy of June 4, 2016. Tr. 56-57, 62. I ruled at the hearing that changing the start date of immediate jeopardy is not a matter of correcting a typographical error, but is instead a substantive change in the enforcement remedy proposed by CMS that would increase the CMP by more than \$120,000. Tr. 65-66. Pursuant to 42 C.F.R. § 498.30, CMS can only reopen and revise its initial determination within 12 months of the date on the notice of the initial determination. Counsel raised this issue for the first time during the first day of hearing on July 16, 2018, more than a year after the date of the initial determination and too late for CMS to reopen and revise its initial determination. Tr. 66-67.

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6. A \$12,541 per-day CMP from June 14 through October 5, 2016, the period of immediate jeopardy, and a \$303 per-day CMP from October 6 through December 11, 2016, a total CMP of \$1,449,975, is a reasonable enforcement remedy.

Petitioner did not request review of the noncompliance cited as violations of 42 C.F.R. §§ 483.20(k)(3)(i) (Tag F281) (s/s D), 483.35(i) (Tag F371) (s/s E), and 483.70(h)(4) (Tag F469) (s/s E); those citations of noncompliance are administratively final; and the citations are bases for the imposition of enforcement remedies. Petitioner also did not request review of the reasonableness of the \$303 per-day CMP based on the unchallenged noncompliance citations for the period October 6 through December 11, 2016, and that remedy is administratively final and not subject to further review for reasonableness. I have concluded that Petitioner violated 42 C.F.R. § 483.65 and that the violation posed a risk for more than minimal harm to one or more facility residents. I have also concluded that Petitioner failed to meet its burden to show that the declaration of immediate jeopardy was clearly erroneous. Therefore, it is necessary to assess the reasonableness of the CMP CMS proposes for the period of immediate jeopardy.

If a facility is not in substantial compliance with program requirements, CMS has the authority to impose one or more of the enforcement remedies listed in 42 C.F.R. § 488.406, including a CMP. CMS may impose a per-day CMP for the number of days that the facility is not in compliance or a per-instance CMP for

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each instance that a facility is not in substantial compliance, whether or not the deficiencies pose immediate jeopardy. 42 C.F.R. § 488.430(a).

A CMP that is imposed against a facility on a per day basis will fall into one of two ranges of penalties. 42 C.F.R. §§ 488.408, 488.438. Relevant here, the upper range of a CMP, \$6,291 per day to \$20,628 per day, is reserved for deficiencies that pose immediate jeopardy to a facility's residents and, in some circumstances, for repeated deficiencies. 42 C.F.R. § 488.438(a)(1)(i), (d)(2); 45 C.F.R. § 102.3 (Table).

I conclude that there is a basis for the imposition of a per-day CMP based on the noncompliance that posed immediate jeopardy in this case. If I conclude, as I have in this case, that there is a basis for the imposition of an enforcement remedy and the remedy proposed is a CMP, my authority to review the reasonableness of the CMP is limited by 42 C.F.R. § 488.438(e). The limitations are: (1) I may not set the CMP at zero or reduce it to zero; (2) I may not review the exercise of discretion by CMS in selecting to impose a CMP; and (3) I may only consider the factors specified by 42 C.F.R. § 488.438(f) when determining the reasonableness of the CMP amount. In determining whether the amount of a CMP is reasonable, the following factors specified at 42 C.F.R. § 488.438(f) must be considered: (1) the facility's history of non-compliance, including repeated deficiencies; (2) the facility's financial condition; (3) the seriousness of the deficiencies as set forth at 42 C.F.R. § 488.404(b), the same factors CMS and/or the state were to consider when setting the CMP amount; and (4) the facility's degree of culpability, including but not limited to the

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facility's neglect, indifference, or disregard for resident care, comfort, and safety, and the absence of culpability is not a mitigating factor. The factors that CMS and the state were required to consider when setting the CMP amount and that I am required to consider when assessing the reasonableness of the amount are set forth in 42 C.F.R. § 488.404(b): (1) whether the deficiencies caused no actual harm but had the potential for minimal harm, no actual harm with the potential for more than minimal harm, but not immediate jeopardy, actual harm that is not immediate jeopardy, or immediate jeopardy to resident health and safety; and (2) whether the deficiencies are isolated, constitute a pattern, or are widespread. My review of the reasonableness of the CMP is de novo and based upon the evidence in the record before me. I am not bound to defer to the CMS determination of the reasonable amount of the CMP to impose, but my authority is limited by regulation as already explained. I am to determine whether the amount of any CMP proposed is within reasonable bounds considering the purpose of the Act and regulations. *Emerald Oaks*, DAB No. 1800 at 10 (2001); *CarePlex of Silver Spring*, DAB No. 1683 at 14-16 (1999); *Capitol Hill Cmty. Rehab. & Specialty Care Ctr.*, DAB No. 1629 (1997).

In this case, CMS proposes to impose a \$12,541 per-day CMP, which is in the middle of the range of CMPs that may be imposed for immediate jeopardy. I find the penalty amount more than justified based on the facts in this case. Petitioner knew it had 18 to 19 residents who required treatment for latent TB infection, but failed to comply with its own infection control policy that required those residents be evaluated and

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treated for latent TB infection. Petitioner's failure resulted in one resident converting to active TB, exposing more residents to the risk of infection with TB and serious harm or death. Petitioner was culpable as staff knew the situation but chose to wait for action by the county health department rather than aggressively pursue evaluation and treatment for the residents. Petitioner failed to deliver necessary care and services and neglected the needs of its residents.³¹ Resident 1 suffered actual harm due to her conversion from latent TB infection to active TB. CMS Ex. 5 at 6. Because 18 to 19 residents were involved and there were two TB outbreaks, there was a pattern of non-compliance. Petitioner has not alleged that its financial condition is grounds for a reduction of the CMP amount. The evidence shows that Petitioner has a history of noncompliance as it was cited with immediate jeopardy in 2014 for a violation of the requirement to deliver necessary care and services. CMS Ex. 21 at 2.

I conclude that a \$12,541 per-day CMP from June 14 through October 5, 2016 is reasonable. I further conclude that the total CMP of \$1,449,975, is reasonable.

III. Conclusion

For the foregoing reasons, I conclude that Petitioner was not in substantial compliance with program participation requirements from June 14 through December 11, 2016. There is a basis for the imposition of the following enforcement remedies,

³¹ I recognize that CMS did not charge Petitioner for either failure to deliver necessary care and services or neglect. I consider only the practical effect of Petitioner's action.

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which are also reasonable: a \$12,541 per-day CMP effective June 14, 2016, through October 5, 2016; and a \$303 per-day CMP effective October 6, 2016, through December 11, 2016.

Keith W. Sickendick

Keith W. Sickendick

Administrative Law Judge

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DEPARTMENT OF HEALTH & HUMAN
SERVICES

Centers for Medicare & Medicaid Services
Suite 216, The Public Ledger Building
150 S. Independence Mall, West
Philadelphia, PA 19106-3413

Northeast Consortium/Division of
Survey & Certification

January 31, 2017

Mr. Eduardo Salazar, Administrator
Sligo Creek Center
7525 Carroll Avenue
Takoma Park, MD 20912

**IMPORTANT NOTICE – PLEASE READ
CAREFULLY**

Dear Mr. Salazar

Re: CMS Certification Number: **215327**

After a careful review of the facts, the Department of Health & Human Services, Centers for Medicare & Medicaid Services (CMS), has determined that **Sligo Creek Center** no longer meets the requirements for participation as a provider of services in the Health Insurance Program for the Aged and Disabled (Medicare) established under Title XVIII of the Social Security Act (the Act), and Medicaid, Title XIX of the Act.

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To participate in the Medicare program as a provider of skilled nursing facility services, a facility must meet all of the provisions of section 1819 (b), (c), and (d) of the Act. In addition, a skilled nursing facility must be in compliance with the Requirements for Long Term Care Facilities established by the Secretary of Health and Human Services, and be free of hazards to the health and safety of residents. If that facility participates in the Medicaid program, it must also meet all of the provisions of sections 1919 (b), (c), and (d) of the Act.

On October 6, 2016, a complaint survey was completed at your facility by the Maryland Office of Health Care Quality (State survey agency) to determine if your facility was in compliance with the Federal participation requirements for nursing homes participating in the Medicare and/or Medicaid programs. The survey determined that your facility was not in substantial compliance with these requirements. The most serious deficiency cited in your facility at the time of this survey, F441 -- S/S: K -- 483.65 -- Infection Control, Prevent Spread, Linens, was cited at a "K" level, which represented a pattern of immediate jeopardy to resident health or safety.

The State survey agency determined on October 6, 2016 that the immediate jeopardy had been removed. However, the following deficiencies remained:

F371 -- S/S: E -- 483.35(i) -- Food Procure, Store/prepare/serve - Sanitary

F469 -- S/S: E -- 483.70(h)(4) -- Maintains Effective Pest Control Program

F520 -- S/S: C -- 483.75(o)(1) -- Qaa Committee-Members/meet Quarterly/plans

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As a result of the survey findings listed on the Statement of Deficiencies (Form CMS 2567), which were forwarded to you by the State survey agency after the survey listed above, we are imposing a civil money penalty (CMP) on your facility.

In accordance with sections 1819(h)(2)(B)(ii) and 1919(h)(3)(C)(ii) of the Social Security Act, and with the enforcement regulations specified at 42 Code of Federal Regulations (CFR), Part 488, we are imposing a CMP on your facility effective June 14, 2016 in the amount of \$13,341.00 for each of the 114 days of immediate jeopardy (June 14, 2016 through October 05, 2016). On October 6, 2016 the immediate jeopardy situation was removed. Effective October 6, 2016, the amount of the CMP is reduced to \$303.00 per day.

The survey agency completed a revisit at your facility on December 12, 2016, and determined that your facility had regained substantial compliance as of December 12, 2016. Therefore, in accordance with sections 1819(h)(2)(B)(ii) and 1919(h)(3)(C)(ii) of the Social Security Act and the enforcement regulations specified at 42 C.F.R. Part 488, we have imposed the following:

Federal Civil Money Penalty of \$303.00 per day for the sixty-seven (67) days beginning October 6, 2016 and continuing through December 11, 2016 for a total of \$20,301.00.

Federal Civil Money Penalty of \$12,541.00 per day for the one hundred fourteen (114) days beginning June 14, 2016 and continuing through October 5, 2016 for a total of \$1,429,674.00.

The total amount of the CMP is \$1,449,975.00. In determining the amount of the CMP, we considered the recommendation of the State survey agency, the

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scope and severity of the deficiencies, the facility's history of non-compliance, including repeated deficiencies, the facility's degree of culpability, and the financial condition of the facility, in addition to the factors specified in 42 C.F.R. § 488.404.

It is not CMS's intent to impose CMPs that could, in and of themselves, put providers out of business. Consequently, if the provider has compelling evidence of financial hardship, we are willing, in the interest of the Medicare program and its beneficiaries, to consider a reduction in the CMP, or an extended repayment plan.

In order to properly consider your request to decrease the CMP because of financial hardship, we must review financial data from the provider. You must submit the attached documentation within fifteen (15) calendar days for a complete evaluation of your request.

Independent Informal Dispute Resolution (IIDR)

In accordance with 42 C.F.R. § 488.431, when a civil money penalty subject to being collected and placed in an escrow account is imposed, you have one opportunity to question cited deficiencies through an IIDR process. You may also contest scope and severity assessments for deficiencies which resulted in a finding of Substandard Quality of Care (SQC) or immediate jeopardy. To be given such an opportunity, you are required to send your written request, along with the specific deficiencies being disputed, and an explanation of why you are disputing those deficiencies (or

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why you are disputing the scope and severity assessments of deficiencies which have been found to constitute SQC or immediate jeopardy) to:

Tricia Nay, MD, Executive Director
Office of Health Care Quality
Department of Health & Mental Hygiene
Bland Bryant Building
Spring Grove Hospital Center
55 Wade Avenue
Catonsville, MD 21228
(410) 402-8001
(410) 402-8015

The State survey agency will convey your request to the entity which has been designated to conduct the IIDRs in Maryland. This request must be sent within 10 calendar days of the receipt of this letter. An incomplete IIDR process will not delay the effective date of any enforcement action.

Appeal Rights

If you disagree with this action imposed on your facility, you or your legal representative may request a hearing before an administrative law judge of the Department of Health and Human Services, Departmental Appeals Board (DAB). Procedures governing this process are set out in 42 C.F.R. § 498.40, et seq. You must file your hearing request electronically by using the Departmental Appeals Board's Electronic Filing System (DAB E-File) at <https://dab.efile.hhs.gov> not later than sixty (60) days after receiving this letter. Specific instructions on how to file electronically are attached to this notice. A copy of the hearing request shall be submitted to:

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Jan M. Lundelius, Chief Counsel
Office of the General Counsel
Public Ledger Building, Suite 418
150 South Independence Mall West
Philadelphia, PA 19106

Requests for a hearing submitted by U.S. mail or commercial carrier are no longer accepted as of October 1, 2014, unless you do not have access to a computer or Internet service. In those circumstances you may call the Civil Remedies Division to request a waiver from e-filing and provide an explanation as to why you cannot file electronically or you may mail a written request for a waiver along with your written request for a hearing. A written request for a hearing must be filed no later than sixty (60) days after receiving this letter, by mailing to the following address:

Department of Health & Human Services
Departmental Appeals Board, MS 6132
Director, Civil Remedies Division
330 Independence Avenue, S.W.
Cohen Building – Room G-644
Washington, D.C. 20201
(202) 565-9462

A request for hearing should identify the specific issues and the findings of fact and conclusions of law with which you disagree, 42 C.F.R. § 498.40(b)(1). It should also specify the basis for contending that the findings and conclusions are incorrect, 42 C.F.R. § 498.40(b)(2). You may be represented by counsel at a hearing, at your own expense.

If you waive your right to a hearing regarding the imposition of the CMP, in accordance with the requirements specified at 42 C.F.R. § 488.436, the

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amount of the CMP will be reduced by thirty-five percent (35%). Waiver of your right to a hearing on the CMP constitutes your admission of the validity of the deficiencies for which the CMP was imposed, and would also preclude you from contesting those deficiencies for any other purpose, e.g., to appeal a denial of payment for new admissions to your facility or to appeal a termination of your provider agreement. Waiver of your right to a hearing on the CMP would, however, not preclude you from contesting the validity of other deficiencies that may be the basis (or part of the basis) for some other action by CMS, e.g., a denial of payments for new admissions or a termination of your provider agreement.

If you would like to waive your right to a hearing, you must do so by submitting your written notice of waiver to the following address within (60) calendar days from the date of this notice:

Pat McNeal
Centers for Medicare & Medicaid Services
Suite 216, The Public Ledger Bldg
150 S. Independence Mall West
Philadelphia, PA 19106

Do not send payment at this time. When we receive notice that you have elected the option to waive your right to appeal the civil money penalty and agree to pay the reduced amount of the CMP, we will provide payment instructions to you.

If a hearing is requested, the full amount of the civil money penalty will be collected and held in an escrow account, pending the final administrative decision, 42 C.F.R. § 488.431(b). We will notify you of the payment methodology. CMS will retain the escrowed funds on

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an on-going basis and, upon a final administrative decision, will either return applicable funds in accordance with 42 C.F.R. § 488.431(d)(2) or, in the case of an unsuccessful administrative appeal, will periodically disburse the funds to States or other entities in accordance with 42 C.F.R. § 488.433.

If you neither submit a written request for a hearing nor formally waive your right to appeal you will be assessed the full amount of the civil money penalty. We will notify you of the payment methodology.

If you have any questions, please contact Pat McNeal at (215) 861-4663 or by email at pat.mcneal@cms.hhs.gov.

Sincerely,

Roxanne Rocco

Roxanne Rocco, Manager
Certification and Enforcement Branch

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Required Documentation for Financial Hardship Claim

- Written, dated request specifying the reason financial hardship is alleged
- Brief summary listing the supporting documents that are being submitted
- Current balance sheet
- Current income statements
- Current cash flow statements
- Most recent full year audited financial statements prepared by an independent accounting firm (including footnotes)
- Most recent full year audited financial statements of the home office and/or related entities (including footnotes)
- Disclosure of expenses and amounts paid/acrued to the home office and/or related entities
- Schedule showing amounts due to/from related companies, or individuals, included in the balance sheets. The schedule should list the names of related organizations, or persons, and indicate where the amounts appear on the balance sheet (e.g., Accounts Receivable, Notes Receivable, etc.)
- If the nursing home requests an extended payment schedule of more than twelve (12) months duration, the provider must submit a letter from a financial institution denying the provider's loan request for the amount of the CMP.

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How to Use the Departmental Appeals Board's Electronic Filing System (DAB E-File) **<https://dab.efile.hhs.gov>**

To file a new appeal using DAB E-File, you first must register a new account by: (1) clicking **Register** on the DAB E-File home page; (2) entering the information requested on the “Register New Account” form; and (3) clicking **Register Account** at the bottom of the form. If you have more than one representative handling your appeal, each representative must register separately to use DAB E-File on your behalf.

How to log-in to E-File. To access DAB E-File, the e-mail address and password provided during the registration process must be entered on the **Login** screen at https://dab.efile.hhs.gov/user_sessions/new. A registered user's access to DAB E-File is restricted to the appeals for which s/he is a party or authorized representative.

How to file an appeal (request for hearing) in DAB E-File. After you have registered and logged-in to DAB E-File, you may file an appeal by: (A) clicking the **File New Appeal** link on the **Manage Existing Appeals** page, then at the next page clicking the **Civil Remedies Division** button; then (B) entering and uploading the requested information and documents on the form labeled “File New Appeal — Civil Remedies Division.”

Basic requirements for using DAB E-File. At a minimum, the DAB's Civil Remedies Division (CRD) requires a party filing an appeal to submit the following: (1) a signed hearing request; and (2) a copy of the underlying notice letter from CMS which sets forth CMS's adverse action and the party's appeal rights.

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All documents must be submitted in Portable Document Format (PDF). Any document, including a hearing request, will be deemed to have been filed on the date it is submitted via DAB E-File (through 11:59 p.m. EST on the date of submission). A party filing a hearing request via DAB E-File will be deemed to have consented to receiving and accepting electronic service of appeal-related documents which CMS subsequently submits via DAB E-File and/or which the CRD subsequently submits via DAB E-File on behalf of an Administrative Law Judge. CMS also will be deemed to have consented to electronic service.

Detailed information regarding DAB E-File. More detailed instructions for using DAB E-File in cases before the DAB's Civil Remedies Division can be found by clicking the button marked E-Filing Instructions; after logging-in to DAB E-File.

For general questions regarding the DAB E-File System, you may call the Civil Remedies Division main telephone line at 202-565-9462. If you experience any technical issues with the DAB E-File System, please contact E-File System Support at

OSDABImmediateOffice@hhs.gov.

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U.S. Const. amend. VII

In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise re-examined in any Court of the United States, than according to the rules of the common law.

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42 U.S.C. § 1320a-7a

(a) Improperly filed claims

Any person (including an organization, agency, or other entity, but excluding a beneficiary, as defined in subsection (i)(5)) that—

(1) knowingly presents or causes to be presented to an officer, employee, or agent of the United States, or of any department or agency thereof, or of any State agency (as defined in subsection (i)(1)), a claim (as defined in subsection (i)(2)) that the Secretary determines—

(A) is for a medical or other item or service that the person knows or should know was not provided as claimed, including any person who engages in a pattern or practice of presenting or causing to be presented a claim for an item or service that is based on a code that the person knows or should know will result in a greater payment to the person than the code the person knows or should know is applicable to the item or service actually provided,

(B) is for a medical or other item or service and the person knows or should know the claim is false or fraudulent,

(C) is presented for a physician's service (or an item or service incident to a physician's service) by a person who knows or should know that the individual who furnished (or supervised the furnishing of) the service—

(i) was not licensed as a physician,

(ii) was licensed as a physician, but such license had been obtained through a misrepresentation of material fact (including cheating on an examination required for licensing), or

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(iii) represented to the patient at the time the service was furnished that the physician was certified in a medical specialty by a medical specialty board when the individual was not so certified,

(D) is for a medical or other item or service furnished during a period in which the person was excluded from the Federal health care program (as defined in section 1320a-7b(f) of this title) under which the claim was made pursuant to Federal law.¹

(E) is for a pattern of medical or other items or services that a person knows or should know are not medically necessary;

(2) knowingly presents or causes to be presented to any person a request for payment which is in violation of the terms of (A) an assignment under section 1395u(b)(3)(B)(ii) of this title, or (B) an agreement with a State agency (or other requirement of a State plan under subchapter XIX) not to charge a person for an item or service in excess of the amount permitted to be charged, or (C) an agreement to be a participating physician or supplier under section 1395u(h)(1) of this title, or (D) an agreement pursuant to section 1395cc(a)(1)(G) of this title;

(3) knowingly gives or causes to be given to any person, with respect to coverage under subchapter XVIII of inpatient hospital services subject to the provisions of section 1395ww of this title, information that he knows or should know is false or misleading, and that could reasonably be expected to influence the decision

¹ So in original. Probably should be “law, or”.

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when to discharge such person or another individual from the hospital;

(4) in the case of a person who is not an organization, agency, or other entity, is excluded from participating in a program under subchapter XVIII or a State health care program in accordance with this subsection or under section 1320a-7 of this title and who, at the time of a violation of this subsection—

(A) retains a direct or indirect ownership or control interest in an entity that is participating in a program under subchapter XVIII or a State health care program, and who knows or should know of the action constituting the basis for the exclusion; or

(B) is an officer or managing employee (as defined in section 1320a-5(b) of this title) of such an entity;

(5) offers to or transfers remuneration to any individual eligible for benefits under subchapter XVIII of this chapter, or under a State health care program (as defined in section 1320a-7(h) of this title) that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under subchapter XVIII, or a State health care program (as so defined);

(6) arranges or contracts (by employment or otherwise) with an individual or entity that the person knows or should know is excluded from participation in a Federal health care program (as defined in section 1320a-7b(f) of this title), for the provision of items or services for which payment may be made under such a program;

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(7) commits an act described in paragraph (1) or (2) of section 1320a-7b(b) of this title;

(8)² knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim for payment for items and services furnished under a Federal health care program; or³

(9)⁴ fails to grant timely access, upon reasonable request (as defined by the Secretary in regulations), to the Inspector General of the Department of Health and Human Services, for the purpose of audits, investigations, evaluations, or other statutory functions of the Inspector General of the Department of Health and Human Services;

(8)² orders or prescribes a medical or other item or service during a period in which the person was excluded from a Federal health care program (as so defined), in the case where the person knows or should know that a claim for such medical or other item or service will be made under such a program;

(9)⁴ knowingly makes or causes to be made any false statement, omission, or misrepresentation of a material fact in any application, bid, or contract to participate or enroll as a provider of services or a supplier under a Federal health care program (as so defined), including Medicare Advantage organizations under part C of subchapter XVIII, prescription drug plan sponsors under part D of subchapter XVIII, medicaid managed care organizations under subchapter XIX, and entities that apply to participate as providers of

² So in original. Two pars. (8) have been enacted.

³ So in original. The word “or” probably should not appear.

⁴ So in original. Two pars. (9) have been enacted.

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services or suppliers in such managed care organizations and such plans;⁵

(10) knows of an overpayment (as defined in paragraph (4) of section 1320a-7k(d) of this title) and does not report and return the overpayment in accordance with such section;

shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty of not more than \$20,000 for each item or service (or, in cases under paragraph (3), \$30,000 for each individual with respect to whom false or misleading information was given; in cases under paragraph (4), \$20,000 for each day the prohibited relationship occurs; in cases under paragraph (7), \$100,000 for each such act,⁶ in cases under paragraph (8),⁷ \$100,000 for each false record or statement,⁶ or³ in cases under paragraph (9),⁸ \$15,000 for each day of the failure described in such paragraph);⁹ or in cases under paragraph (9),¹⁰ \$100,000 for each false statement or misrepresentation of a material fact). In addition, such a person shall be subject to an assessment of not more than 3 times the amount claimed for each such item or service in lieu of damages sustained by the United States or a State agency because of such claim (or, in cases under paragraph (7), damages of not more than 3

⁵ So in original. Probably should be followed by “or”.

⁶ So in original. The comma probably should be a semicolon.

⁷ So in original. Probably is a reference to the first paragraph (8).

⁸ So in original. Probably is a reference to the first paragraph (9).

⁹ So in original. Probably should be “paragraph;”.

¹⁰ So in original. Probably is a reference to the second paragraph (9).

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times the total amount of remuneration offered, paid, solicited, or received, without regard to whether a portion of such remuneration was offered, paid, solicited, or received for a lawful purpose; or in cases under paragraph (9), an assessment of not more than 3 times the total amount claimed for each item or service for which payment was made based upon the application containing the false statement or misrepresentation of a material fact). In addition the Secretary may make a determination in the same proceeding to exclude the person from participation in the Federal health care programs (as defined in section 1320a-7b(f)(1) of this title) and to direct the appropriate State agency to exclude the person from participation in any State health care program.

(b) Payments to induce reduction or limitation of services

(1) If a hospital or a critical access hospital knowingly makes a payment, directly or indirectly, to a physician as an inducement to reduce or limit medically necessary services provided with respect to individuals who—

(A) are entitled to benefits under part A or part B of subchapter XVIII or to medical assistance under a State plan approved under subchapter XIX, and

(B) are under the direct care of the physician, the hospital or a critical access hospital shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty of not more than \$5,000 for each such individual with respect to whom the payment is made.

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(2) Any physician who knowingly accepts receipt of a payment described in paragraph (1) shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty of not more than \$5,000 for each individual described in such paragraph with respect to whom the payment is made.

(3)(A) Any physician who executes a document described in subparagraph (B) with respect to an individual knowing that all of the requirements referred to in such subparagraph are not met with respect to the individual shall be subject to a civil monetary penalty of not more than the greater of—

(i) \$10,000, or

(ii) three times the amount of the payments under subchapter XVIII for home health services which are made pursuant to such certification.

(B) A document described in this subparagraph is any document that certifies, for purposes of subchapter XVIII, that an individual meets the requirements of section 1395f(a)(2)(C) or 1395n(a)(2)(A) of this title in the case of home health services furnished to the individual.

(c) Initiation of proceeding; authorization by Attorney General, notice, etc., estoppel, failure to comply with order or procedure

(1) The Secretary may initiate a proceeding to determine whether to impose a civil money penalty, assessment, or exclusion under subsection (a) or (b) only as authorized by the Attorney General pursuant to procedures agreed upon by them. The Secretary may not initiate an action under this section with respect to any claim, request for payment, or other occurrence

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described in this section later than six years after the date the claim was presented, the request for payment was made, or the occurrence took place. The Secretary may initiate an action under this section by serving notice of the action in any manner authorized by Rule 4 of the Federal Rules of Civil Procedure.

(2) The Secretary shall not make a determination adverse to any person under subsection (a) or (b) until the person has been given written notice and an opportunity for the determination to be made on the record after a hearing at which the person is entitled to be represented by counsel, to present witnesses, and to cross-examine witnesses against the person.

(3) In a proceeding under subsection (a) or (b) which—

(A) is against a person who has been convicted (whether upon a verdict after trial or upon a plea of guilty or nolo contendere) of a Federal crime charging fraud or false statements, and

(B) involves the same transaction as in the criminal action,

the person is estopped from denying the essential elements of the criminal offense.

(4) The official conducting a hearing under this section may sanction a person, including any party or attorney, for failing to comply with an order or procedure, failing to defend an action, or other misconduct as would interfere with the speedy, orderly, or fair conduct of the hearing. Such sanction shall reasonably relate to the severity and nature of the failure or misconduct. Such sanction may include—

(A) in the case of refusal to provide or permit discovery, drawing negative factual inferences or

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treating such refusal as an admission by deeming the matter, or certain facts, to be established,

(B) prohibiting a party from introducing certain evidence or otherwise supporting a particular claim or defense,

(C) striking pleadings, in whole or in part,

(D) staying the proceedings,

(E) dismissal of the action,

(F) entering a default judgment,

(G) ordering the party or attorney to pay attorneys' fees and other costs caused by the failure or misconduct, and

(H) refusing to consider any motion or other action which is not filed in a timely manner.

(d) Amount or scope of penalty, assessment, or exclusion

In determining the amount or scope of any penalty, assessment, or exclusion imposed pursuant to subsection (a) or (b), the Secretary shall take into account—

(1) the nature of claims and the circumstances under which they were presented,

(2) the degree of culpability, history of prior offenses, and financial condition of the person presenting the claims, and

(3) such other matters as justice may require.

(e) Review by courts of appeals

Any person adversely affected by a determination of the Secretary under this section may obtain a review of such determination in the United States Court of Appeals for the circuit in which the person resides, or

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in which the claim or specified claim was presented, by filing in such court (within sixty days following the date the person is notified of the Secretary's determination) a written petition requesting that the determination be modified or set aside. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary, and thereupon the Secretary shall file in the Court¹¹ the record in the proceeding as provided in section 2112 of title 28. Upon such filing, the court shall have jurisdiction of the proceeding and of the question determined therein, and shall have the power to make and enter upon the pleadings, testimony, and proceedings set forth in such record a decree affirming, modifying, remanding for further consideration, or setting aside, in whole or in part, the determination of the Secretary and enforcing the same to the extent that such order is affirmed or modified. No objection that has not been urged before the Secretary shall be considered by the court, unless the failure or neglect to urge such objection shall be excused because of extraordinary circumstances. The findings of the Secretary with respect to questions of fact, if supported by substantial evidence on the record considered as a whole, shall be conclusive. If any party shall apply to the court for leave to adduce additional evidence and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the hearing before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be made a part of the record. The Secretary may modify his findings

¹¹ So in original. Probably should not be capitalized.

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as to the facts, or make new findings, by reason of additional evidence so taken and filed, and he shall file with the court such modified or new findings, which findings with respect to questions of fact, if supported by substantial evidence on the record considered as a whole, shall be conclusive, and his recommendations, if any, for the modification or setting aside of his original order. Upon the filing of the record with it, the jurisdiction of the court shall be exclusive and its judgment and decree shall be final, except that the same shall be subject to review by the Supreme Court of the United States, as provided in section 1254 of title 28.

(f) Compromise of penalties and assessments; recovery; use of funds recovered

Civil money penalties and assessments imposed under this section may be compromised by the Secretary and may be recovered in a civil action in the name of the United States brought in United States district court for the district where the claim or specified claim (as defined in subsection (r)) was presented, or where the claimant (or, with respect to a person described in subsection (o), the person) resides, as determined by the Secretary. Amounts recovered under this section shall be paid to the Secretary and disposed of as follows:

(1)(A) In the case of amounts recovered arising out of a claim under subchapter XIX, there shall be paid to the State agency an amount bearing the same proportion to the total amount recovered as the State's share of the amount paid by the State agency for such claim bears to the total amount paid for such claim.

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(B) In the case of amounts recovered arising out of a claim under an allotment to a State under subchapter V, there shall be paid to the State agency an amount equal to three sevenths of the amount recovered.

(2) Such portion of the amounts recovered as is determined to have been paid out of the trust funds under sections 1395i and 1395t of this title shall be repaid to such trust funds.

(3) With respect to amounts recovered arising out of a claim under a Federal health care program (as defined in section 1320a-7b(f) of this title), the portion of such amounts as is determined to have been paid by the program shall be repaid to the program, and the portion of such amounts attributable to the amounts recovered under this section by reason of the amendments made by the Health Insurance Portability and Accountability Act of 1996 (as estimated by the Secretary) shall be deposited into the Federal Hospital Insurance Trust Fund pursuant to section 1395i(k)(2)(C) of this title.

(4) The remainder of the amounts recovered shall be deposited as miscellaneous receipts of the Treasury of the United States.

The amount of such penalty or assessment, when finally determined, or the amount agreed upon in compromise, may be deducted from any sum then or later owing by the United States or a State agency (or, in the case of a penalty or assessment under subsection (o), by a specified State agency (as defined in subsection (q)(6)), to the person against whom the penalty or assessment has been assessed.

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(g) Finality of determination respecting penalty, assessment, or exclusion

A determination by the Secretary to impose a penalty, assessment, or exclusion under subsection (a) or (b) shall be final upon the expiration of the sixty-day period referred to in subsection (e). Matters that were raised or that could have been raised in a hearing before the Secretary or in an appeal pursuant to subsection (e) may not be raised as a defense to a civil action by the United States to collect a penalty, assessment, or exclusion assessed under this section.

(h) Notification of appropriate entities of finality of determination

Whenever the Secretary's determination to impose a penalty, assessment, or exclusion under subsection (a) or (b) becomes final, he shall notify the appropriate State or local medical or professional organization, the appropriate State agency or agencies administering or supervising the administration of State health care programs (as defined in section 1320a-7(h) of this title), and the appropriate utilization and quality control peer review organization, and the appropriate State or local licensing agency or organization (including the agency specified in section 1395aa(a) and 1396a(a)(33) of this title) that such a penalty, assessment, or exclusion has become final and the reasons therefor.

(i) Definitions

For the purposes of this section:

(1) The term "State agency" means the agency established or designated to administer or supervise the administration of the State plan under subchapter XIX of this chapter or designated to administer

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the State's program under subchapter V or division A¹² of subchapter XX of this chapter.

(2) The term “claim” means an application for payments for items and services under a Federal health care program (as defined in section 1320a-7b(f) of this title).

(3) The term “item or service” includes (A) any particular item, device, medical supply, or service claimed to have been provided to a patient and listed in an itemized claim for payment, and (B) in the case of a claim based on costs, any entry in the cost report, books of account or other documents supporting such claim.

(4) The term “agency of the United States” includes any contractor acting as a fiscal intermediary, carrier, or fiscal agent or any other claims processing agent for a Federal health care program (as so defined).

(5) The term “beneficiary” means an individual who is eligible to receive items or services for which payment may be made under a Federal health care program (as so defined) but does not include a provider, supplier, or practitioner.

(6) The term “remuneration” includes the waiver of coinsurance and deductible amounts (or any part thereof), and transfers of items or services for free or for other than fair market value. The term “remuneration” does not include—

(A) the waiver of coinsurance and deductible amounts by a person, if—

¹² See References in Text note below.

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- (i) the waiver is not offered as part of any advertisement or solicitation;
- (ii) the person does not routinely waive coinsurance or deductible amounts; and
- (iii) the person—

- (I) waives the coinsurance and deductible amounts after determining in good faith that the individual is in financial need; or

- (II) fails to collect coinsurance or deductible amounts after making reasonable collection efforts;

- (B) subject to subsection (n), any permissible practice described in any subparagraph of section 1320a-7b(b)(3) of this title or in regulations issued by the Secretary;

- (C) differentials in coinsurance and deductible amounts as part of a benefit plan design as long as the differentials have been disclosed in writing to all beneficiaries, third party payers, and providers, to whom claims are presented and as long as the differentials meet the standards as defined in regulations promulgated by the Secretary not later than 180 days after August 21, 1996;

- (D) incentives given to individuals to promote the delivery of preventive care as determined by the Secretary in regulations so promulgated;

- (E) a reduction in the copayment amount for covered OPD services under section 1395l(t)(5)(B)¹² of this title; or³

- (F) any other remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs (as defined in

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section 1320a–7b(f) of this title and designated by the Secretary under regulations);

(G) the offer or transfer of items or services for free or less than fair market value by a person, if—

(i) the items or services consist of coupons, rebates, or other rewards from a retailer;

(ii) the items or services are offered or transferred on equal terms available to the general public, regardless of health insurance status; and

(iii) the offer or transfer of the items or services is not tied to the provision of other items or services reimbursed in whole or in part by the program under subchapter XVIII or a State health care program (as defined in section 1320a-7(h) of this title);

(H) the offer or transfer of items or services for free or less than fair market value by a person, if—

(i) the items or services are not offered as part of any advertisement or solicitation;

(ii) the items or services are not tied to the provision of other services reimbursed in whole or in part by the program under subchapter XVIII or a State health care program (as so defined);

(iii) there is a reasonable connection between the items or services and the medical care of the individual; and

(iv) the person provides the items or services after determining in good faith that the individual is in financial need;

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(I) effective on a date specified by the Secretary (but not earlier than January 1, 2011), the waiver by a PDP sponsor of a prescription drug plan under part D of subchapter XVIII or an MA organization offering an MA–PD plan under part C of such subchapter of any copayment for the first fill of a covered part D drug (as defined in section 1395w-102(e) of this title) that is a generic drug for individuals enrolled in the prescription drug plan or MA–PD plan, respectively; or

(J) the provision of telehealth technologies (as defined by the Secretary) on or after January 1, 2019, by a provider of services or a renal dialysis facility (as such terms are defined for purposes of subchapter XVIII) to an individual with end stage renal disease who is receiving home dialysis for which payment is being made under part B of such subchapter, if—

(i) the telehealth technologies are not offered as part of any advertisement or solicitation;

(ii) the telehealth technologies are provided for the purpose of furnishing telehealth services related to the individual’s end stage renal disease; and

(iii) the provision of the telehealth technologies meets any other requirements set forth in regulations promulgated by the Secretary.

(7) The term “should know” means that a person, with respect to information—

(A) acts in deliberate ignorance of the truth or falsity of the information; or

(B) acts in reckless disregard of the truth or falsity of the information,

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and no proof of specific intent to defraud is required.

(j) Subpoenas

(1) The provisions of subsections (d) and (e) of section 405 of this title shall apply with respect to this section to the same extent as they are applicable with respect to subchapter II. The Secretary may delegate the authority granted by section 405(d) of this title (as made applicable to this section) to the Inspector General of the Department of Health and Human Services for purposes of any investigation under this section.

(2) The Secretary may delegate authority granted under this section and under section 1320a-7 of this title to the Inspector General of the Department of Health and Human Services.

(k) Injunctions

Whenever the Secretary has reason to believe that any person has engaged, is engaging, or is about to engage in any activity which makes the person subject to a civil monetary penalty under this section, the Secretary may bring an action in an appropriate district court of the United States (or, if applicable, a United States court of any territory) to enjoin such activity, or to enjoin the person from concealing, removing, encumbering, or disposing of assets which may be required in order to pay a civil monetary penalty if any such penalty were to be imposed or to seek other appropriate relief.

(l) Liability of principal for acts of agent

A principal is liable for penalties, assessments, and an exclusion under this section for the actions of the principal's agent acting within the scope of the agency.

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(m) Claims within jurisdiction of other departments or agencies

(1) For purposes of this section, with respect to a Federal health care program not contained in this chapter, references to the Secretary in this section shall be deemed to be references to the Secretary or Administrator of the department or agency with jurisdiction over such program and references to the Inspector General of the Department of Health and Human Services in this section shall be deemed to be references to the Inspector General of the applicable department or agency.

(2)(A) The Secretary and Administrator of the departments and agencies referred to in paragraph (1) may include in any action pursuant to this section, claims within the jurisdiction of other Federal departments or agencies as long as the following conditions are satisfied:

(i) The case involves primarily claims submitted to the Federal health care programs of the department or agency initiating the action.

(ii) The Secretary or Administrator of the department or agency initiating the action gives notice and an opportunity to participate in the investigation to the Inspector General of the department or agency with primary jurisdiction over the Federal health care programs to which the claims were submitted.

(B) If the conditions specified in subparagraph

(A) are fulfilled, the Inspector General of the department or agency initiating the action is authorized to exercise all powers granted under chapter 4 of title 5 with respect to the claims submitted to

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the other departments or agencies to the same manner and extent as provided in that Act with respect to claims submitted to such departments or agencies.

(n) Safe harbor for payment of medigap premiums

(1) Subparagraph (B) of subsection (i)(6) shall not apply to a practice described in paragraph

(2) unless—

(A) the Secretary, through the Inspector General of the Department of Health and Human Services, promulgates a rule authorizing such a practice as an exception to remuneration; and

(B) the remuneration is offered or transferred by a person under such rule during the 2-year period beginning on the date the rule is first promulgated.

(2) A practice described in this paragraph is a practice under which a health care provider or facility pays, in whole or in part, premiums for medicare supplemental policies for individuals entitled to benefits under part A of subchapter XVIII pursuant to section 426-1 of this title.

(o) Penalties for violations of grants, contracts, and other agreements

Any person (including an organization, agency, or other entity, but excluding a program beneficiary, as defined in subsection (q)(4)) that, with respect to a grant, contract, or other agreement for which the Secretary provides funding—

(1) knowingly presents or causes to be presented a specified claim (as defined in subsection (r)) under

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such grant, contract, or other agreement that the person knows or should know is false or fraudulent;

(2) knowingly makes, uses, or causes to be made or used any false statement, omission, or misrepresentation of a material fact in any application, proposal, bid, progress report, or other document that is required to be submitted in order to directly or indirectly receive or retain funds provided in whole or in part by such Secretary pursuant to such grant, contract, or other agreement;

(3) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent specified claim under such grant, contract, or other agreement;

(4) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation (as defined in subsection (s)) to pay or transmit funds or property to such Secretary with respect to such grant, contract, or other agreement, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit funds or property to such Secretary with respect to such grant, contract, or other agreement; or

(5) fails to grant timely access, upon reasonable request (as defined by such Secretary in regulations), to the Inspector General of the Department, for the purpose of audits, investigations, evaluations, or other statutory functions of such Inspector General in matters involving such grants, contracts, or other agreements;

shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty in cases under paragraph (1), of not more than \$10,000 for each specified claim; in cases under paragraph (2),

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not more than \$50,000 for each false statement, omission, or misrepresentation of a material fact; in cases under paragraph (3), not more than \$50,000 for each false record or statement; in cases under paragraph (4), not more than \$50,000 for each false record or statement or \$10,000 for each day that the person knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay; or in cases under paragraph (5), not more than \$15,000 for each day of the failure described in such paragraph. In addition, in cases under paragraphs (1) and (3), such a person shall be subject to an assessment of not more than 3 times the amount claimed in the specified claim described in such paragraph in lieu of damages sustained by the United States or a specified State agency because of such specified claim, and in cases under paragraphs (2) and (4), such a person shall be subject to an assessment of not more than 3 times the total amount of the funds described in paragraph (2) or (4), respectively (or, in the case of an obligation to transmit property to the Secretary described in paragraph (4), of the value of the property described in such paragraph) in lieu of damages sustained by the United States or a specified State agency because of such case. In addition, the Secretary may make a determination in the same proceeding to exclude the person from participation in the Federal health care programs (as defined in section 1320a-7b(f)(1) of this title) and to direct the appropriate State agency to exclude the person from participation in any State health care program.

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(p) Applicability of rules to penalties or assessments for violations of grants, contracts, and other agreements

The provisions of subsections (c), (d), (g), and (h) shall apply to a civil money penalty or assessment under subsection (o) in the same manner as such provisions apply to a penalty, assessment, or proceeding under subsection (a). In applying subsection (d), each reference to a claim under such subsection shall be treated as including a reference to a specified claim (as defined in subsection (r)).

(q) Definitions of terms used in subsections (o) and (p)

For purposes of this subsection and subsections (o) and (p):

(1) The term “Department” means the Department of Health and Human Services.

(2) The term “material” means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

(3) The term “other agreement” includes a cooperative agreement, scholarship, fellowship, loan, subsidy, payment for a specified use, donation agreement, award, or subaward (regardless of whether one or more of the persons entering into the agreement is a contractor or subcontractor).

(4) The term “program beneficiary” means, in the case of a grant, contract, or other agreement designed to accomplish the objective of awarding or otherwise furnishing benefits or assistance to individuals and for which the Secretary provides funding, an individual who applies for, or who receives,

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such benefits or assistance from such grant, contract, or other agreement. Such term does not include, with respect to such grant, contract, or other agreement, an officer, employee, or agent of a person or entity that receives such grant or that enters into such contract or other agreement.

(5) The term “recipient” includes a subrecipient or subcontractor.

(6) The term “specified State agency” means an agency of a State government established or designated to administer or supervise the administration of a grant, contract, or other agreement funded in whole or in part by the Secretary.

(r) Definition of “specified claim”

For purposes of this section, the term “specified claim” means any application, request, or demand under a grant, contract, or other agreement for money or property, whether or not the United States or a specified State agency has title to the money or property, that is not a claim (as defined in subsection (i)(2)) and that—

(1) is presented or caused to be presented to an officer, employee, or agent of the Department or agency thereof, or of any specified State agency; or

(2) is made to a contractor, grantee, or any other recipient if the money or property is to be spent or used on the Department’s behalf or to advance a Department program or interest, and if the Department—

(A) provides or has provided any portion of the money or property requested or demanded; or

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(B) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.

(s) Definition of “obligation”

For purposes of subsection (o), the term “obligation” means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, for a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment.

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42 U.S.C. § 1395i-3 (d), (g)-(h)

(d) Requirements relating to administration and other matters

(1) Administration

(A) In general

A skilled nursing facility must be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial wellbeing of each resident (consistent with requirements established under subsection (f)(5)).

(B) Skilled nursing facility administrator

The administrator of a skilled nursing facility must meet standards established by the Secretary under subsection (f)(4).

(C) Availability of survey, certification, and complaint investigation reports

A skilled nursing facility must—

(i) have reports with respect to any surveys, certifications, and complaint investigations made respecting the facility during the 3 preceding years available for any individual to review upon request; and

(ii) post notice of the availability of such reports in areas of the facility that are prominent and accessible to the public.

The facility shall not make available under clause (i) identifying information about complainants or residents.

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(2) Licensing and Life Safety Code

(A) Licensing

A skilled nursing facility must be licensed under applicable State and local law.

(B) Life Safety Code

A skilled nursing facility must meet such provisions of such edition (as specified by the Secretary in regulation) of the Life Safety Code of the National Fire Protection Association as are applicable to nursing homes; except that—

(i) the Secretary may waive, for such periods as he deems appropriate, specific provisions of such Code which if rigidly applied would result in unreasonable hardship upon a facility, but only if such waiver would not adversely affect the health and safety of residents or personnel, and

(ii) the provisions of such Code shall not apply in any State if the Secretary finds that in such State there is in effect a fire and safety code, imposed by State law, which adequately protects residents of and personnel in skilled nursing facilities.

(3) Sanitary and infection control and physical environment

A skilled nursing facility must—

(A) establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment in which residents reside and to help prevent the development and transmission of disease and infection, and

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(B) be designed, constructed, equipped, and maintained in a manner to protect the health and safety of residents, personnel, and the general public.

(4) Miscellaneous

(A) Compliance with Federal, State, and local laws and professional standards

A skilled nursing facility must operate and provide services in compliance with all applicable Federal, State, and local laws and regulations (including the requirements of section 1320a-3 of this title) and with accepted professional standards and principles which apply to professionals providing services in such a facility.

(B) Other

A skilled nursing facility must meet such other requirements relating to the health, safety, and well-being of residents or relating to the physical facilities thereof as the Secretary may find necessary.

* * *

(g) Survey and certification process

(1) State and Federal responsibility

(A) In general

Pursuant to an agreement under section 1395aa of this title, each State shall be responsible for certifying, in accordance with surveys conducted under paragraph (2), the compliance of skilled nursing facilities (other than facilities of the State) with the requirements of subsections (b), (c), and (d). The Secretary shall be responsible for certifying, in

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accordance with surveys conducted under paragraph (2), the compliance of State skilled nursing facilities with the requirements of such subsections.

(B) Educational program

Each State shall conduct periodic educational programs for the staff and residents (and their representatives) of skilled nursing facilities in order to present current regulations, procedures, and policies under this section.

(C) Investigation of allegations of resident neglect and abuse and misappropriation of resident property

The State shall provide, through the agency responsible for surveys and certification of nursing facilities under this subsection, for a process for the receipt and timely review and investigation of allegations of neglect and abuse and misappropriation of resident property by a nurse aide of a resident in a nursing facility or by another individual used by the facility in providing services to such a resident. The State shall, after providing the individual involved with a written notice of the allegations (including a statement of the availability of a hearing for the individual to rebut the allegations) and the opportunity for a hearing on the record, make a written finding as to the accuracy of the allegations. If the State finds that a nurse aide has neglected or abused a resident or misappropriated resident property in a facility, the State shall notify the nurse aide and the registry of such finding. If the State finds that any other individual used by the facility has ne-

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glected or abused a resident or misappropriated resident property in a facility, the State shall notify the appropriate licensure authority. A State shall not make a finding that an individual has neglected a resident if the individual demonstrates that such neglect was caused by factors beyond the control of the individual.

(D) Removal of name from nurse aide registry

(i) In general

In the case of a finding of neglect under subparagraph (C), the State shall establish a procedure to permit a nurse aide to petition the State to have his or her name removed from the registry upon a determination by the State that—

(I) the employment and personal history of the nurse aide does not reflect a pattern of abusive behavior or neglect; and

(II) the neglect involved in the original finding was a singular occurrence.

(ii) Timing of determination

In no case shall a determination on a petition submitted under clause (i) be made prior to the expiration of the 1-year period beginning on the date on which the name of the petitioner was added to the registry under subparagraph (C).

(E) Construction

The failure of the Secretary to issue regulations to carry out this subsection shall not relieve a State of its responsibility under this subsection.

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(2) Surveys

(A) Standard survey

(i) In general

Each skilled nursing facility shall be subject to a standard survey, to be conducted without any prior notice to the facility. Any individual who notifies (or causes to be notified) a skilled nursing facility of the time or date on which such a survey is scheduled to be conducted is subject to a civil money penalty of not to exceed \$2,000. The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title. The Secretary shall review each State's procedures for the scheduling and conduct of standard surveys to assure that the State has taken all reasonable steps to avoid giving notice of such a survey through the scheduling procedures and the conduct of the surveys themselves.

(ii) Contents

Each standard survey shall include, for a case-mix stratified sample of residents—

(I) a survey of the quality of care furnished, as measured by indicators of medical, nursing, and rehabilitative care, dietary and nutrition services, activities and social participation, and sanitation, infection control, and the physical environment,

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(II) written plans of care provided under subsection (b)(2) and an audit of the residents' assessments under subsection (b)(3) to determine the accuracy of such assessments and the adequacy of such plans of care, and

(III) a review of compliance with residents' rights under subsection (c).

(iii) Frequency

(I) In general

Each skilled nursing facility shall be subject to a standard survey not later than 15 months after the date of the previous standard survey conducted under this subparagraph. The Statewide average interval between standard surveys of skilled nursing facilities under this subsection shall not exceed 12 months.

(II) Special surveys

If not otherwise conducted under subclause (I), a standard survey (or an abbreviated standard survey) may be conducted within 2 months of any change of ownership, administration, management of a skilled nursing facility, or the director of nursing in order to determine whether the change has resulted in any decline in the quality of care furnished in the facility.

(B) Extended surveys

(i) In general

Each skilled nursing facility which is found, under a standard survey, to have provided substandard quality of care shall be subject to an extended survey. Any other facility may, at the Secretary's

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or State's discretion, be subject to such an extended survey (or a partial extended survey).

(ii) Timing

The extended survey shall be conducted immediately after the standard survey (or, if not practicable, not later than 2 weeks after the date of completion of the standard survey).

(iii) Contents

In such an extended survey, the survey team shall review and identify the policies and procedures which produced such substandard quality of care and shall determine whether the facility has complied with all the requirements described in subsections (b), (c), and (d). Such review shall include an expansion of the size of the sample of residents' assessments reviewed and a review of the staffing, of in-service training, and, if appropriate, of contracts with consultants.

(iv) Construction

Nothing in this paragraph shall be construed as requiring an extended or partial extended survey as a prerequisite to imposing a sanction against a facility under subsection (h) on the basis of findings in a standard survey.

(C) Survey protocol

Standard and extended surveys shall be conducted—

- (i) based upon a protocol which the Secretary has developed, tested, and validated by not later than January 1, 1990, and

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(ii) by individuals, of a survey team, who meet such minimum qualifications as the Secretary establishes by not later than such date.

The failure of the Secretary to develop, test, or validate such protocols or to establish such minimum qualifications shall not relieve any State of its responsibility (or the Secretary of the Secretary's responsibility) to conduct surveys under this subsection.

(D) Consistency of surveys

Each State and the Secretary shall implement programs to measure and reduce inconsistency in the application of survey results among surveyors.

(E) Survey teams

(i) In general

Surveys under this subsection shall be conducted by a multidisciplinary team of professionals (including a registered professional nurse).

(ii) Prohibition of conflicts of interest

A State may not use as a member of a survey team under this subsection an individual who is serving (or has served within the previous 2 years) as a member of the staff of, or as a consultant to, the facility surveyed respecting compliance with the requirements of subsections (b), (c), and (d), or who has a personal or familial financial interest in the facility being surveyed.

(iii) Training

The Secretary shall provide for the comprehensive training of State and Federal surveyors in the conduct

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of standard and extended surveys under this subsection, including the auditing of resident assessments and plans of care. No individual shall serve as a member of a survey team unless the individual has successfully completed a training and testing program in survey and certification techniques that has been approved by the Secretary.

(3) Validation surveys

(A) In general

The Secretary shall conduct onsite surveys of a representative sample of skilled nursing facilities in each State, within 2 months of the date of surveys conducted under paragraph (2) by the State, in a sufficient number to allow inferences about the adequacies of each State's surveys conducted under paragraph (2). In conducting such surveys, the Secretary shall use the same survey protocols as the State is required to use under paragraph (2). If the State has determined that an individual skilled nursing facility meets the requirements of subsections (b), (c), and (d), but the Secretary determines that the facility does not meet such requirements, the Secretary's determination as to the facility's noncompliance with such requirements is binding and supersedes that of the State survey.

(B) Scope

With respect to each State, the Secretary shall conduct surveys under subparagraph

(A) each year with respect to at least 5 percent of the number of skilled nursing facilities surveyed by the State in the year, but in no case less than 5 skilled nursing facilities in the State.

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(C) Remedies for substandard performance

If the Secretary finds, on the basis of such surveys, that a State has failed to perform surveys as required under paragraph (2) or that a State's survey and certification performance otherwise is not adequate, the Secretary shall provide for an appropriate remedy, which may include the training of survey teams in the State.

(D) Special surveys of compliance

Where the Secretary has reason to question the compliance of a skilled nursing facility with any of the requirements of subsections (b), (c), and (d), the Secretary may conduct a survey of the facility and, on the basis of that survey, make independent and binding determinations concerning the extent to which the skilled nursing facility meets such requirements.

(4) Investigation of complaints and monitoring compliance

Each State shall maintain procedures and adequate staff to—

(A) investigate complaints of violations of requirements by skilled nursing facilities, and

(B) monitor, on-site, on a regular, as needed basis, a skilled nursing facility's compliance with the requirements of subsections (b), (c), and (d), if—

(i) the facility has been found not to be in compliance with such requirements and is in the process of correcting deficiencies to achieve such compliance;

(ii) the facility was previously found not to be in compliance with such requirements, has corrected deficiencies to achieve such compliance,

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and verification of continued compliance is indicated; or

(iii) the State has reason to question the compliance of the facility with such requirements.

A State may maintain and utilize a specialized team (including an attorney, an auditor, and appropriate health care professionals) for the purpose of identifying, surveying, gathering and preserving evidence, and carrying out appropriate enforcement actions against substandard skilled nursing facilities.

(5) Disclosure of results of inspections and activities

(A) Public information

Each State, and the Secretary, shall make available to the public—

(i) information respecting all surveys and certifications made respecting skilled nursing facilities, including statements of deficiencies, within 14 calendar days after such information is made available to those facilities, and approved plans of correction,

(ii) copies of cost reports of such facilities filed under this subchapter or subchapter XIX,

(iii) copies of statements of ownership under section 1320a-3 of this title, and

(iv) information disclosed under section 1320a-5 of this title.

(B) Notice to ombudsman

Each State shall notify the State long-term care ombudsman (established under title III or VII of the Older Americans Act of 1965 [42 U.S.C. 3021 et seq.,

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3058 et seq.] in accordance with section 712 of the Act [42 U.S.C. 3058g]) of the State's findings of noncompliance with any of the requirements of subsections (b), (c), and (d), or of any adverse action taken against a skilled nursing facility under paragraph (1), (2), or (4) of subsection (h), with respect to a skilled nursing facility in the State.

(C) Notice to physicians and skilled nursing facility administrator licensing board

If a State finds that a skilled nursing facility has provided substandard quality of care, the State shall notify—

- (i) the attending physician of each resident with respect to which such finding is made, and
- (ii) the State board responsible for the licensing of the skilled nursing facility administrator at the facility.

(D) Access to fraud control units

Each State shall provide its State medicaid fraud and abuse control unit (established under section 1396b(q) of this title) with access to all information of the State agency responsible for surveys and certifications under this subsection.

(E) Submission of survey and certification information to the Secretary

In order to improve the timeliness of information made available to the public under subparagraph (A) and provided on the Nursing Home Compare Medicare website under subsection (i), each State shall submit information respecting any survey or certifica-

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tion made respecting a skilled nursing facility (including any enforcement actions taken by the State) to the Secretary not later than the date on which the State sends such information to the facility. The Secretary shall use the information submitted under the preceding sentence to update the information provided on the Nursing Home Compare Medicare website as expeditiously as practicable but not less frequently than quarterly.

(h) Enforcement process

(1) In general

If a State finds, on the basis of a standard, extended, or partial extended survey under subsection (g)(2) or otherwise, that a skilled nursing facility no longer meets a requirement of subsection (b), (c), or (d), and further finds that the facility's deficiencies—

(A) immediately jeopardize the health or safety of its residents, the State shall recommend to the Secretary that the Secretary take such action as described in paragraph (2)(A)(i); or

(B) do not immediately jeopardize the health or safety of its residents, the State may recommend to the Secretary that the Secretary take such action as described in paragraph (2)(A)(ii).

If a State finds that a skilled nursing facility meets the requirements of subsections (b), (c), and (d), but, as of a previous period, did not meet such requirements, the State may recommend a civil money penalty under paragraph (2)(B)(ii) for the days in which it finds that the facility was not in compliance with such requirements.

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(2) Secretarial authority

(A) In general

With respect to any skilled nursing facility in a State, if the Secretary finds, or pursuant to a recommendation of the State under paragraph (1) finds, that a skilled nursing facility no longer meets a requirement of subsection (b), (c), (d), or (e), and further finds that the facility's deficiencies—

(i) immediately jeopardize the health or safety of its residents, the Secretary shall take immediate action to remove the jeopardy and correct the deficiencies through the remedy specified in subparagraph (B)(iii), or terminate the facility's participation under this subchapter and may provide, in addition, for one or more of the other remedies described in subparagraph (B); or

(ii) do not immediately jeopardize the health or safety of its residents, the Secretary may impose any of the remedies described in subparagraph (B). Nothing in this subparagraph shall be construed as restricting the remedies available to the Secretary to remedy a skilled nursing facility's deficiencies. If the Secretary finds, or pursuant to the recommendation of the State under paragraph (1) finds, that a skilled nursing facility meets such requirements but, as of a previous period, did not meet such requirements, the Secretary may provide for a civil money penalty under subparagraph (B)(ii) for the days on which he finds that the facility was not in compliance with such requirements.

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(B) Specified remedies

The Secretary may take the following actions with respect to a finding that a facility has not met an applicable requirement:

(i) Denial of payment

The Secretary may deny any further payments under this subchapter with respect to all individuals entitled to benefits under this subchapter in the facility or with respect to such individuals admitted to the facility after the effective date of the finding.

(ii) Authority with respect to civil money penalties

(I) In general

Subject to subclause (II), the Secretary may impose a civil money penalty in an amount not to exceed \$10,000 for each day of noncompliance. The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

(II) Reduction of civil money penalties in certain circumstances

Subject to subclause (III), in the case where a facility self-reports and promptly corrects a deficiency for which a penalty was imposed under this clause not later than 10 calendar days after the date of such imposition, the Secretary may reduce

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the amount of the penalty imposed by not more than 50 percent.

(III) Prohibitions on reduction for certain deficiencies

(aa) Repeat deficiencies

The Secretary may not reduce the amount of a penalty under subclause (II) if the Secretary had reduced a penalty imposed on the facility in the preceding year under such subclause with respect to a repeat deficiency.

(bb) Certain other deficiencies

The Secretary may not reduce the amount of a penalty under subclause (II) if the penalty is imposed on the facility for a deficiency that is found to result in a pattern of harm or widespread harm, immediately jeopardizes the health or safety of a resident or residents of the facility, or results in the death of a resident of the facility.

(IV) Collection of civil money penalties

In the case of a civil money penalty imposed under this clause, the Secretary shall issue regulations that—

(aa) subject to item (cc), not later than 30 days after the imposition of the penalty, provide for the facility to have the opportunity to participate in an independent informal dispute resolution process which generates a written record prior to the collection of such penalty;

(bb) in the case where the penalty is imposed for each day of noncompliance, provide

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that a penalty may not be imposed for any day during the period beginning on the initial day of the imposition of the penalty and ending on the day on which the informal dispute resolution process under item (aa) is completed;

(cc) may provide for the collection of such civil money penalty and the placement of such amounts collected in an escrow account under the direction of the Secretary on the earlier of the date on which the informal dispute resolution process under item (aa) is completed or the date that is 90 days after the date of the imposition of the penalty;

(dd) may provide that such amounts collected are kept in such account pending the resolution of any subsequent appeals;

(ee) in the case where the facility successfully appeals the penalty, may provide for the return of such amounts collected (plus interest) to the facility; and

(ff) in the case where all such appeals are unsuccessful, may provide that some portion of such amounts collected may be used to support activities that benefit residents, including assistance to support and protect residents of a facility that closes (voluntarily or involuntarily) or is decertified (including offsetting costs of relocating residents to home and community-based settings or another facility), projects that support resident and family councils and other consumer involvement in assuring quality care in facilities,

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and facility improvement initiatives approved by the Secretary (including joint training of facility staff and surveyors, technical assistance for facilities implementing quality assurance programs, the appointment of temporary management firms, and other activities approved by the Secretary).

(iii) Appointment of temporary management

In consultation with the State, the Secretary may appoint temporary management to oversee the operation of the facility and to assure the health and safety of the facility's residents, where there is a need for temporary management while—

- (I) there is an orderly closure of the facility, or
- (II) improvements are made in order to bring the facility into compliance with all the requirements of subsections (b), (c), and (d).

The temporary management under this clause shall not be terminated under subclause (II) until the Secretary has determined that the facility has the management capability to ensure continued compliance with all the requirements of subsections (b), (c), and (d).

The Secretary shall specify criteria, as to when and how each of such remedies is to be applied, the amounts of any fines, and the severity of each of these remedies, to be used in the imposition of such remedies. Such criteria shall be designed so as to minimize the time between the identification of violations and final imposition of the remedies and shall provide for the imposition of incrementally more severe fines for

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repeated or uncorrected deficiencies. In addition, the Secretary may provide for other specified remedies, such as directed plans of correction.

(C) Continuation of payments pending remediation

The Secretary may continue payments, over a period of not longer than 6 months after the effective date of the findings, under this subchapter with respect to a skilled nursing facility not in compliance with a requirement of subsection (b), (c), or (d), if—

- (i) the State survey agency finds that it is more appropriate to take alternative action to assure compliance of the facility with the requirements than to terminate the certification of the facility,
- (ii) the State has submitted a plan and timetable for corrective action to the Secretary for approval and the Secretary approves the plan of corrective action, and
- (iii) the facility agrees to repay to the Federal Government payments received under this subparagraph if the corrective action is not taken in accordance with the approved plan and timetable.

The Secretary shall establish guidelines for approval of corrective actions requested by States under this subparagraph.

(D) Assuring prompt compliance

If a skilled nursing facility has not complied with any of the requirements of subsections (b), (c), and (d), within 3 months after the date the facility is found to be out of compliance with such requirements, the Sec-

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retary shall impose the remedy described in subparagraph (B)(i) for all individuals who are admitted to the facility after such date.

(E) Repeated noncompliance

In the case of a skilled nursing facility which, on 3 consecutive standard surveys conducted under subsection (g)(2), has been found to have provided substandard quality of care, the Secretary shall (regardless of what other remedies are provided)—

- (i) impose the remedy described in subparagraph (B)(i), and
- (ii) monitor the facility under subsection (g)(4)(B) until the facility has demonstrated, to the satisfaction of the Secretary, that it is in compliance with the requirements of subsections (b), (c), and (d), and that it will remain in compliance with such requirements.

(3) Effective period of denial of payment

A finding to deny payment under this subsection shall terminate when the Secretary finds that the facility is in substantial compliance with all the requirements of subsections (b), (c), and (d).

(4) Immediate termination of participation for facility where Secretary finds noncompliance and immediate jeopardy

If the Secretary finds that a skilled nursing facility has not met a requirement of subsection (b), (c), or (d), and finds that the failure immediately jeopardizes the health or safety of its residents, the Secretary shall take immediate action to remove the jeopardy and correct the deficiencies through the remedy specified in

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paragraph (2)(B)(iii), or the Secretary, subject to section 1320a-7j(h) of this title, shall terminate the facility's participation under this subchapter. If the facility's participation under this subchapter is terminated, the State shall provide for the safe and orderly transfer of the residents eligible under this subchapter consistent with the requirements of subsection (c)(2) and section 1320a-7j(h) of this title.

(5) Construction

The remedies provided under this subsection are in addition to those otherwise available under State or Federal law and shall not be construed as limiting such other remedies, including any remedy available to an individual at common law. The remedies described in clauses (i), (ii)(IV), and (iii) of paragraph (2)(B) may be imposed during the pendency of any hearing.

(6) Sharing of information

Notwithstanding any other provision of law, all information concerning skilled nursing facilities required by this section to be filed with the Secretary or a State agency shall be made available by such facilities to Federal or State employees for purposes consistent with the effective administration of programs established under this subchapter and subchapter XIX, including investigations by State medicaid fraud control units.