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

Karim Maghareh, Ph.D. and BestCare Laboratory Services, LLC Docket No. A-18-127 Decision No. 2919 December 27, 2018

## FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Petitioners Karim Maghareh, Ph.D. and BestCare Laboratory Services, LLC (BestCare) appeal the August 17, 2018 decision of an Administrative Law Judge (ALJ) to exclude them from federal health care programs for 15 years, as proposed by the Department of Health & Human Services Office of Inspector General (I.G.). *Karim Maghareh, Ph.D., et al.*, DAB CR5166 (ALJ Decision). The ALJ concluded that Petitioners are subject to exclusion under section 1128(b)(7) of the Social Security Act<sup>1</sup> because they knowingly filed Medicare claims for mileage-based travel allowances that they knew or should have known were false. The ALJ also concluded that 15 years is a reasonable period of exclusion under the circumstances. Petitioners contest these conclusions, but we hold that they are supported by substantial evidence and free of legal error. In addition, we decline to entertain Petitioners' apparent challenge to the ALJ's authority under the Constitution's Appointment Clause because they failed to raise that matter before the ALJ. Accordingly, we affirm the ALJ's decision.

## I. Legal Background

## A. The I.G.'s exclusion authority

Section 1128(b)(7) of the Act authorizes the Secretary of Health and Human Services (Secretary) to exclude from participation in federal health care programs "[a]ny individual or entity that [he] determines has committed an act which is described in section 1128A" of the Act. The acts described in section 1128A include "knowingly present[ing] or caus[ing] to be presented to an officer, employee, or agent of the United

<sup>&</sup>lt;sup>1</sup> The current version of the Social Security Act can be found at

<sup>&</sup>lt;u>http://www.socialsecurity.gov/OP\_Home/ssact/ssact.htm</u>. Each section of the Act on that website contains a reference to the corresponding United States Code chapter and section. Also, a cross-reference table for the Act and the United States Code can be found at <u>https://www.ssa.gov/OP\_Home/comp2/G-APP-H.html</u>.

States, or of any department or agency thereof . . ., *a claim* . . . 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 . . . . [or] (B) is for a medical or other item or service and the person knows or *should know* the claim is false or fraudulent" (italics added). Act § 1128A(a)(1) (italics added). A "claim," as defined in section 1128A, is "an application for payments for items and services under a Federal health care program," and the words "should know" mean "that a person, with respect to information[,] . . . acts in deliberate ignorance," or in "reckless disregard," of the information's truth or falsity. *Id.* § 1128A(i)(2), (7).

A person the I.G. has proposed to exclude under section 1128 of the Act may request a hearing before an ALJ, but only on the issues of: (1) whether there is a "basis for . . . imposition" of the exclusion; and (2) whether "[t]he length of exclusion [imposed by the I.G.] is unreasonable." 45 C.F.R. § 1001.2007(a). A party dissatisfied with an ALJ's decision may appeal to the Board. *Id.* § 1005.21(a).

### B. Medicare payment for diagnostic laboratory tests and related services

The Medicare program, established under title XVIII (sections 1801 *et seq.*) of the Act, provides health insurance benefits to persons 65 years and older and other groups. The program's benefits are defined in federal law. *See, e.g.*, Act §§ 1812, 1832. The Centers for Medicare & Medicaid Services (CMS), a component of the Department of Health and Human Services, has overall responsibility for administering Medicare. CMS delegates some of its Medicare administrative responsibilities (such as claims processing) to contractors.

Part B of Medicare pays for the performance of diagnostic laboratory tests under a clinical laboratory fee schedule.<sup>2</sup> *See* Act § 1833(h)(1); 42 C.F.R. § 410.32. In addition to paying for a laboratory test's performance, Part B makes two other test-related payments to a laboratory (when appropriate). The first, not at issue here, is a "nominal fee to cover the appropriate costs in collecting the [laboratory test] sample" – called a "specimen collection fee" – from the Medicare beneficiary. Act § 1833(h)(3)(A). The second payment, known as a "travel allowance," is described in section 1833(h)(3)(B) of the Medicare statute as --

<sup>&</sup>lt;sup>2</sup> Part A also covers diagnostic laboratory tests when provided to a Medicare beneficiary during the course of a covered hospital or skilled nursing facility stay. *See* Medicare Claims Processing Manual (CMS Pub. 100-04), Ch. 16, § 30.3 (available at <u>https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS018912.html</u>). The Medicare claims at issue in this case sought payment under Part B, not Part A.

a fee to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect the sample, except that such a fee may be provided only with respect to an individual who is homebound or an inpatient in an inpatient facility (other than a hospital).

Section 1833(h)(3)(B) further directs the Secretary to "provide a method for computing the fee [travel allowance] based on the number of miles traveled and the personnel costs associated with the collection of each individual sample . . . ."

CMS has implemented section 1833(h)(3)(B) in the Medicare Claims Processing Manual (MCPM), a publication that instructs CMS's contractors about Medicare billing, coverage, and payment requirements and policies. Section 60.2 of Chapter 16 of the MCPM (MCPM § 60.2 or section 60.2) states, as it did during the years relevant to this case (*see* P. Ex. 7, at 4-5), that the "travel allowance [authorized under section 1833(h)(3)(B)] is intended to cover the estimated travel cost of collecting a specimen and to reflect the technician's salary and travel costs." Section 60.2 authorizes a contractor to pay either a "per-mile" travel allowance (when the average trip to patients' homes is longer than 20 miles round trip) or a flat-rate-per-trip allowance (to be used in areas where average trips are less than 20 miles round trip). In addition, section 60.2 indicates that the per-mile allowance (about one dollar per mile) should be claimed using Healthcare Common Procedure Coding System (HCPCS) code P9603, and the flat-rate allowance using HCPCS code P9604. The travel-allowance claims at issue in this case were all per-mile claims filed under code P9603.

## II. Case Background<sup>3</sup>

Dr. Maghareh founded BestCare, a clinical laboratory, in 2002. Dr. Maghareh is BestCare's majority owner and chief executive officer.

During 2009 and 2010 (and also in prior years), BestCare performed diagnostic laboratory tests for Medicare beneficiaries throughout Texas. Most of BestCare's Medicare clientele were residents of skilled nursing facilities.

BestCare's primary laboratory was in Webster, Texas, a Houston suburb. BestCare also operated smaller laboratories in San Antonio and Dallas and had offices in Waco, Austin and El Paso. Phlebotomists employed by BestCare in San Antonio, Dallas, and other cities (besides Houston) traveled to nursing homes to collect specimens and then returned

<sup>&</sup>lt;sup>3</sup> The facts stated in this section are undisputed and are drawn from, among other sources, Petitioners' December 5, 2016 pre-hearing brief; Petitioners' December 5, 2016 brief supporting their motion for summary judgment; the declarations of Dr. Maghareh and a BestCare employee named Kari Ramirez (P. Exs. 42-43); and the transcript of March 2018 hearing conducted by the ALJ.

the specimens to BestCare's local laboratories or offices for processing. Some of the collected specimens would be tested or prepped in the local laboratories (in San Antonio or Dallas), but most were brought to the airport and shipped in batches by commercial airline – unaccompanied by a phlebotomist or other trained personnel – to Houston's Hobby Airport, where BestCare employees would pick up the shipments and drive them to the Webster laboratory.

The I.G. found that, from at least August 21, 2009 through January 26, 2010 (the "relevant period"), BestCare submitted to Medicare per-mile travel-allowance claims (under P96303) "for miles not actually travelled by a [laboratory] technician and miles not travelled by a specimen." See P.'s Request for Hearing, Ex. A at 3. In particular, the I.G. found that BestCare "systematically" claimed the per-mile travel allowance for miles that specimens were transported, by air and ground, between various Texas cities (such as Austin and Dallas) and its Webster laboratory, even though a phlebotomist or laboratory technician did not accompany the specimens on these inter-city trips. Id., Ex. A at 2. The I.G. further found that, in some instances, BestCare billed Medicare for "round-trip travel between the Webster laboratory and the address where the specimen was collected and back, when specimens were only shipped one-way or were actually tested locally in the BestCare laboratories in Dallas and San Antonio." Id., Ex. A at 2-3. The I.G. found that BestCare had engaged in these billing practices even though section 1833(h)(3)(B) "expressly states that Medicare only pays for 'trained personnel to travel to the location of an individual to collect the sample," and even though the MCPM made it clear that laboratories could not claim the per-mile travel allowance based on miles not actually traveled by a laboratory technician. Id., Ex. A at 2 (quoting section 1833(h)(3)(B) of the Act). The I.G. calculated that 633 travel-allowance claims submitted by BestCare during the relevant period reflected one or both of the just-described billing practices, resulting in "significant financial harm" to the Medicare program. Id., Ex. A at 3.

Based on these findings, the I.G. concluded that Petitioners had performed acts described in section 1128A(a)(1) – more specifically, that they had knowingly submitted to a federal health care program "claims" for items or services they "knew or should have known were not provided as claimed and were false or fraudulent." *Id.*, Ex. A at 2. The I.G. further determined that Petitioners were, by virtue of those acts, subject to exclusion under section 1128(b)(7) and therefore proposed to exclude them from federal health programs for 15 years. *Id.*, Ex. A at 2, 3. The I.G. notified Petitioners of the proposed exclusion (and supporting findings) in an August 21, 2015 Notice of Proposed Exclusion. *Id.*, Ex. A. Petitioners challenged the proposed exclusion by requesting a hearing before an ALJ. The case was initially assigned to Judge Scott Anderson. In June 2017, the case was transferred to Judge Bill Thomas. Meanwhile the parties engaged in discovery and exchanged documentary evidence and written direct testimony. In March 2018, ALJ Thomas convened a hearing in which the parties cross-examined some of each other's witnesses. The parties filed post-hearing briefs in June 2018, and the ALJ issued his decision approximately two months later.

While this exclusion case was pending before the ALJ, a civil action against Petitioners, based on allegations of improper travel-allowance claiming, was pending in a United States District Court in Houston. The lawsuit was filed in 2008 by the owner of a competing clinical laboratory seeking damages and penalties under the qui tam (whistleblower) provisions of the federal False Claims Act, 31 U.S.C. § 3721-3731. See Oct. 28, 2016 Pre-Hearing Brief of the IG, Attachment C. The United States intervened in the lawsuit in 2011, alleging that from at least 2004 through at least 2009, the "vast majority" of BestCare's Medicare travel-allowance claims under HCPCS code P9603 were false or fraudulent. Id., Attachment D. More specifically, the United States alleged that Petitioners had knowingly submitted false per-mile travel-allowance claims based on mileage that had not been prorated (in violation of rules that a technician's trip miles be prorated by the number of patients served by that trip), for mileage not actually traveled by trained personnel, and for mileage that was not reasonable. Id., Attachment D, ¶ 24-31. For the alleged misconduct, the United States sought penalties and damages under the False Claims Act and under common law theories of fraud, payment by mistake, and unjust enrichment. Id., Attachment D at 12-17.

In August 2014, based on what it called the "most egregious" claims filed by the defendants between August 4, 2005 and January 26, 2010 – claims that in each instance sought a per-mile travel allowance for more than 400 miles of travel – the District Court granted partial summary judgment to the United States on its common law theories of payment by mistake and unjust enrichment, holding that the United States was entitled to recoup \$10.6 million from the defendants. *See* Oct. 28, 2016 Motion for Summary Judgment by the I.G., Attachments A and B. (The August 21, 2015 Notice of Proposed Exclusion indicates that the I.G. considered this partial judgment in deciding how long to exclude Petitioners from federal health programs under section 1128(b)(7) of the Act.)

On April 3, 2018, the District Court granted summary judgment to the United States on its False Claims Act theories, holding that the United States was entitled to treble damages of approximately \$30 million. April 3, 2018 Opinion on Summary Judgment in *United States ex rel. Drummond v. BestCare Laboratory Servs., LLC*, No. 08-02441 (S.D. Tex.) (submitted as docket entry 89A in CRD Dkt. No. C-16-40). The April 3, 2018 grant of summary judgment was based on a motion in which the United States contended that: (1) between August 4, 2005 and June 30, 2008, Petitioners submitted at

least 24,798 per-mile travel-allowance claims, each of which sought payment based on 400 or more miles of travel with respect to a beneficiary's specimen; (2) Medicare paid BestCare \$10,190,545.00 for these claims; (3) the claims falsely represented that BestCare's laboratory technicians (or phlebotomists) had traveled "millions of miles that they did not travel" and that round-trips had occurred even though the specimens were shipped only one-way or were tested locally and barely "traveled" at all; and (4) the defendants acted in reckless disregard that those claims were false. *See* United States' Motion for Partial Summary Judgment under the False Claims Act and Supporting Memorandum, filed on March 18, 2014, in *United States ex rel. Drummond v. BestCare Laboratory Servs., LLC* (submitted as Attachment C to P.'s June 18, 2018 Post-Hearing Br.).

In July 2018, the District Court entered a final judgment in the case. Docket Entries 96a-96b in CRD Dkt. No. C-16-40. An appeal of that judgment is pending in the United States Court of Appeals for the Fifth Circuit.

In a 2016 brief, the I.G. informed the ALJ that, although it believed that the travelallowance billing practices highlighted in its August 21, 2015 Notice of Proposed Exclusion had been occurring since 2005, it would defend the proposed exclusion based solely on travel-allowance claims submitted by Petitioners during the relevant period (August 21, 2009 to January 26, 2010) in order to comport with the statute of limitations in section 1128A(c)(1) of the Act.

#### III. The ALJ's Decision

The ALJ found that the I.G. had identified 571 Medicare per-mile travel-allowance claims that Petitioners had presented, or caused to be presented, to Medicare (under P9603) during the relevant period; that each of those claims was signed by Dr. Maghareh; that his signatures on the claims reflected his understanding that "payment of a claim by Medicare is conditioned upon the claim and underlying transaction complying with [Medicare] laws, regulations, and program instructions"; that each claim sought, on behalf of a beneficiary, an allowance based on at least 400 miles of travel; that in each instance the bulk of the claimed miles represented distance that a laboratory sample was shipped by air while unaccompanied by a laboratory technician or other trained personnel; and that each claim was "false" because "claims for travel mileage of a sample unaccompanied by trained personnel are not permitted under the Act." ALJ Decision at 10-15 (internal quotation marks omitted).

The ALJ further found that, when they submitted the 571 claims in question, Petitioners recklessly disregarded or deliberately ignored Medicare program guidance issued by CMS and Trailblazer Health Enterprises (the Medicare Part B contractor for Texas) which "clearly put [them] on notice that their practice of billing code P9603 for miles traveled by laboratory samples that were not accompanied by a laboratory technician was improper." *Id.* at 17-19, 21, 24-26. In addition, the ALJ rejected Petitioners' contention that they reasonably believed (in 2009 and 2010) that those claims were proper given their reading of MCPM § 60.2, the results of outside audits of BestCare's travel-allowance claims, conversations with a Trailblazer employee named Dean Richardson, and other circumstances. *Id.* at 19-26. The ALJ therefore found that Petitioners "should have known" that the claims in question were false. *Id.* at 14, 26.

Having found that Petitioners had submitted 571 Medicare payment claims that they knew or should have known were false, the ALJ concluded that the criteria for exclusion in section 1128(b)(7) of the Act were met.<sup>4</sup> *Id.* at 7, 10, 13, 14, 26. The ALJ then considered whether the duration of the proposed exclusion (15 years) was reasonable and concluded it was reasonable based on factors specified in the I.G.'s regulations. *Id.* at 28-32.

#### **IV.** Standard of Review

The Board reviews an ALJ's decision in an I.G. exclusion appeal to determine if it is supported by substantial evidence and free of legal error. 45 C.F.R. § 1005.21(h).

#### V. Analysis

As outlined above, the ALJ concluded that Petitioners are subject to exclusion under section 1128(b)(7) because they had "knowingly present[ed] or caus[ed] to be presented" to an "agency of the United States" 571 "claims" (as defined in section 1128A(i)(2)) that they "knew or should have known" were "false or fraudulent." ALJ Decision at 10. Petitioners do not dispute that the claims in question met the definition of "claim" in section 1128A(i)(2). Nor do Petitioners dispute that they knowingly "presented" those claims to an agency of the United States. Petitioners disagree, however, with the ALJ's findings about the claims' falsity and their knowledge of that falsity. Petitioner's Brief in Support of Notice of Appeal (P. Br.) at 6-10, 10-25. They also object to the ALJ's conclusion that 15 years is a reasonable period of exclusion. *Id.* at 25-32. Finally, Petitioners question whether the ALJ had the authority to decide their case in light of *Lucia v. S.E.C.*, 138 S. Ct. 2044 (2018). We address each of these issues below.

<sup>&</sup>lt;sup>4</sup> The ALJ also found the statute of limitations in section 1128A(c)(1) of the Act did not preclude the I.G. from excluding Petitioners based on their submission of claims during the relevant period. ALJ Decision at 27-28. Neither party has raised an issue in this appeal concerning that statute of limitations.

## A. Petitioners identify no error in the ALJ's holding that, during the relevant period, they submitted 571 false per-mile travel-allowance claims.

Petitioners concede that each of the 571 claims at issue (billed to Medicare under HCPCS code P9603) sought a per-mile travel allowance based largely on distance that a specimen was transported by air and ground – while unaccompanied by trained personnel – from BestCare's satellite locations (such as San Antonio and Dallas) to its Webster laboratory; indeed, Petitioners admit that it was their *practice* during (and prior to) the relevant period to claim the per-mile travel allowance in that fashion. P. Br. at 1 (stating that Petitioners "do not dispute" that they "bill[ed] for mileage for transport of specimens drawn from non-Houston area patients to its Houston facility for laboratory testing, when the specimens were transported by airplane without an accompanying laboratory technician"); *see also* Hearing Transcript (Tr.) at 634-38, 643-46, 810; I.G. Ex. 3, at 167-70; P. Ex. 42, at 9-13; P. Ex. 43, at 4-5, 7. The ALJ held that all 571 claims were "false" because "claims for travel mileage of a sample unaccompanied by trained personnel are not permitted under [section 1833(h)(3)(B) of] the Act." ALJ Decision at 13-14.

Petitioners respond to that holding with two arguments. First, they contend that the relevant statute "provides no specificity" about whether a travel allowance may be claimed for miles not traveled by a laboratory technician. P. Br. at 9. Petitioners contend that by instructing the Secretary in section 1833(h)(3)(B) to "provide a method for computing the fee [allowance] based on the number of miles traveled and the personnel costs associated with the collection of each individual sample," Congress left it to CMS to decide "whether the 'number of miles traveled' means the miles traveled by the sample, by the trained personnel, and/or both." Id. We disagree. Section 1833(h)(3)(B) directs Medicare to pay the allowance in order to "cover" the "transportation and personnel expenses for trained personnel to travel to the location of an individual to collect a sample" (italics added). Clearly, in context, "transportation" refers to the travel of trained personnel to collect a specimen from a Medicare beneficiary. There is no other reasonable reading of this statutory language. The statute does not specify or allude to any other categories of "travel" for which the allowance may be paid. Furthermore, the instruction to provide a "method" for computing the allowance does not ask the Secretary to identify the types of "expenses" or miles that the allowance may cover; the instruction rather simply instructs the Secretary to specify a method for measuring a technician's trip-related transportation and personnel expenses based on "miles traveled." For these reasons, we agree with the ALJ that the statute does not permit Medicare to pay a travel allowance based on miles not traveled by trained personnel.<sup>5</sup>

<sup>&</sup>lt;sup>5</sup> Petitioners attempt to distinguish the "purpose" of the travel allowance ("which Congress determined in the Act") from the "method for computing" the allowance ("which Congress left to CMS"). P. Br. at 8. However, this is a false distinction because CMS's computation method must be (and is) consistent with the statutory purpose.

Petitioners secondarily contend that the 571 travel-allowance claims at issue were not false because, in their view, MCPM § 60.2, permitted – or at least did not prohibit – the payment of a per-mile travel allowance for miles "traveled" by an unaccompanied "specimen" in some circumstances. P. Br. at 1-2, 6-10. During the relevant period, MCPM § 60.2 stated:

... Medicare, under Part B, covers a specimen collection fee and a travel allowance for a laboratory technician to draw a specimen from either a nursing home patient or homebound patient under §1833(h)(3) of the Act and payment is made based on the clinical laboratory fee schedule. *The travel allowance is intended to cover the estimated travel costs of collecting a specimen and to reflect the technician's salary and travel costs.* 

The additional allowance can be made only where a specimen collection fee is also payable, i.e., no travel allowance is made where the technician merely performs a messenger service to pick up a specimen drawn by a physician or nursing home personnel. . . .

... The travel allowance is not distributed by CMS. Instead, the carrier must calculate the travel allowance for each claim using the following rules for the particular [HCPCS] Code. The following HCPCS codes are used for travel allowances:

#### Per Mile Travel Allowance (P9603)

- The minimum "per mile travel allowance" is \$1.035. The per mile travel allowance is to be used in situations where the average trip to patients' homes is longer than 20 miles round trip, and is to be pro-rated in situations where specimens are drawn or picked up from non-Medicare patients in the same trip. one way, in connection with medically necessary laboratory specimen collection drawn from homebound or nursing home bound patient; prorated miles actually traveled (carrier allowance on per mile basis); or
- The per mile allowance was computed using the Federal mileage rate plus an additional 45 cents a mile *to cover the technician's time and travel costs*. Contractors have the option of establishing a higher per mile rate in excess of the minimum (1.035 cents a mile in CY 2008) if local conditions warrant it. The minimum mileage

rate will be reviewed and updated in conjunction with the clinical lab fee schedule as needed. *At no time will the laboratory be allowed to bill* for more miles than are reasonable or *for miles not actually traveled by the laboratory technician*.

#### Flat Rate (P9604)

The CMS will pay a minimum of \$9.55 one way flat rate travel allowance. The flat rate travel allowance is to be used in areas where average trips are less than 20 miles round trip. . . . .

P. Ex. 7, at 4-5 (italics added). Apart from the stated dollar values of the mileage and per-trip rates (\$1.035 per mile, \$9.55 per trip), this passage remained unchanged from October 1, 2003 through at least the end of the relevant period. *See* P. Ex. 11, at 5 (indicating a revision date of October 1, 2003 on a version of section 60.2 whose content is identical to the version in effect during the relevant period except for the specified mileage and trip rates).

The ALJ found that "the Secretary's guidance, taken in whole, was not ambiguous." ALJ Decision at 15. He found that MCPM § 60.2 is sensibly read as barring per-mile travelallowance claims based on miles not traveled by trained personnel. ALJ Decision at 17. We concur. Paraphrasing section 1833(h)(3)(B), MCPM § 60.2 states at the outset that the travel allowance is intended to "reflect" salary and travel costs incurred by a "technician" to collect a laboratory specimen from a homebound person or nursing home resident. Section 60.2 also explains that the mileage rate (\$1.035) to be used in claiming the per-mile allowance was established to "cover" the technician's time and travel costs. In addition, section 60.2 states that "*[a]t no time* will the laboratory be allowed to bill . . . for miles not actually traveled by the laboratory technician" (italics added). It clearly follows from these statements that a laboratory may claim the per-mile allowance only for miles that a technician travels to collect a specimen from a homebound patient or nursing home resident. Nowhere does MCPM § 60.2 suggest that the travel allowance may be based on distance that a specimen is shipped after the technician has traveled to collect it.<sup>6</sup> Such a reading is wholly at odds with the description of the allowance as Medicare's estimate of a *technician*'s salary and travel costs.

<sup>&</sup>lt;sup>6</sup> MCPM § 60.2 provided two examples of per-mile travel-allowance claims under P9603. P. Ex. 7, at 5. Both examples (which we do not quote in the text) show a reimbursement amount based on miles traveled by a technician.

Petitioners' view that MCPM § 60.2 permitted them to bill for "specimen travel without an accompanying technician" is founded on its purported reading of the bulleted paragraphs under the heading "Per Mile Travel Allowance (P9603)." The first bulleted paragraph specifies the "minimum" per-mile allowance (\$1.035 per mile), indicates when a per-mile allowance (rather than a per-trip allowance) should be claimed, and discusses when and how the per-mile allowance should be prorated (that is, when specimens are collected from more than one person during a single trip). The second bulleted paragraph discusses how CMS determined the minimum per-mile allowance, states that a contractor has "the option of establishing a higher per mile rate in excess of the minimum," indicates that the minimum mileage rate "will be reviewed and updated . . . as needed," and then states that "[a]t no time will the laboratory be allowed to bill for more miles than are reasonable or for miles not actually traveled by the laboratory technician." P. Ex. 7, at 4-5.

Seizing on the fact that the bulleted paragraphs are separated by the conjunction "or," and noting that the first paragraph (which specifies the minimum mileage rate) does not include a statement prohibiting the billing of miles not traveled by a technician (and refers only to "miles actually traveled"), Petitioners suggest that the paragraphs establish two "distinct" rules during the relevant period: one that *permitted* payment of a per-mile travel allowance based on miles not traveled by trained personnel when the claim for that allowance was made at the minimum mileage rate; and another which prohibited a permile travel allowance based on miles not traveled by trained personnel when the claim was billed to a contractor that had established a mileage rate higher than the minimum. See P. Br. at 7-8, 9 (asserting that in order to give "separate meanings" to the bulleted paragraphs, one can or should read the phrase "miles actually traveled" in the first paragraph to include miles traveled by the specimen "when the per mile allowance is in effect," and to read the phrase "miles . . . actually traveled by laboratory technician" in the second bulleted paragraph as applying only to the "more limited scenario where the Contractors have established 'a higher per mile rate in excess of the minimum'" (internal quotation marks omitted)). Based on that reading and on the fact that their Part B contractor (Trailblazer) paid travel-allowance claims at the minimum mileage rate (and did not establish a higher rate as referenced in the second paragraph), Petitioners assert that the 571 claims in question were allowable, or not expressly barred, and therefore not false. Id. at 7 (asserting that the ALJ erred in "finding that the prohibition against billing for 'miles not actually traveled by a laboratory technician' under Code P9603 applied in every instance of billing under that Code").

Petitioners' reading of the bulleted paragraphs is strained and unreasonable. It conflicts with the statements in MCPM § 60.2 that the travel allowance is intended and designed to cover the *technician's* salary and travel costs. Petitioners' reading is also unsupported by the bulleted paragraphs' text. Nothing there indicates that CMS has established two

alternative mileage-billing rules whose applicability depends on the mileage rate applied by the contractor. If anything, the second bulleted paragraph expressly negates that possibility: after explaining the composition of the minimum mileage rate and stating that a contractor could set a higher rate based on local conditions, the second paragraph states that Medicare "at no time" permits billing based on miles not traveled by a laboratory technician.<sup>7</sup> Given that the second paragraph discusses *both* the minimum mileage rate and the possibility that some contractor might establish a higher rate, the phrase "at no time" clearly signals that billing for miles not traveled by a technician is barred in *all* cases, regardless of the mileage rate used. Petitioners suggest no other plausible meaning of the words "at no time," nor do they say why their reading of MCPM § 60-2 is sensible as a matter of law, policy, or common sense. Given that CMS uses the MCPM to instruct or guide Medicare contactors about program requirements and policies, we do not find it plausible to read the disjunctive reference to a minimum mileage rate or a contractor-set local rate as somehow creating sub silentio an entitlement to payment at the minimum mileage rate when no technician is traveling at all.

On May 30, 2008, CMS issued Change Request 5996 (CR5996), which announced revisions (none material to this case) to MCPM § 60.2. I.G. Ex. 14, at 1, 7-9. In a "General Information" section prefacing its specification of the manual revisions, CR5996 restated – without using the bulleted paragraph format to which Petitioners attach so much significance – that "[a]t no time will the laboratory be allowed to bill for more miles than are reasonable or for miles that are not actually traveled by the laboratory technician." *Id.* at 3. Thus, any purported confusion (which we have already said was not reasonable to begin with) should have been resolved before the relevant period.

Based on the foregoing analysis, we reject Petitioner's contention that section 1833(h)(3)(B) and MCPM § 60.2 permitted, or did not prohibit, per-mile travelallowance claims based on miles not traveled by a laboratory technician or other trained personnel. Petitioners do not assert any other basis for questioning the ALJ's conclusion that the 571 travel-allowance claims at issue in this case were false. We therefore affirm that conclusion.

<sup>&</sup>lt;sup>7</sup> That the conjunction "or" appears between the two bulleted paragraphs is insignificant given that the paragraphs' text and MCPM § 60.2 as a whole clearly foreclose Petitioners' strained reading. Furthermore, the conjunction's purpose is not entirely clear but appears to draw the reader's attention to the fact that the per-mile travel allowance may be based on the minimum mileage rate established by CMS or on some higher rate established by a contractor to reflect local conditions.

As we have stated above, we find the statutory language clear that the travel costs were only for trained personnel doing specimen collection and we agree with the ALJ that MCPM § 60.2 did not contradict that requirement. We also agree with the ALJ that, in addition to the statutory requirement (which Petitioners as Medicare participants were charged with knowing), ample additional evidence demonstrates that Petitioners "should have known" that their travel-allowance claims during the relevant period were false. Specifically, to the extent their claims were based on air and ground miles not traveled by trained personnel, Petitioners recklessly disregarded or deliberately ignored multiple sources of Medicare program guidance that expressly and "clearly" prohibited billing for such mileage.<sup>8</sup> ALJ Decision at 17, 18-26 (finding that Medicare program guidance "clearly instructed" Petitioners "that they could only bill Medicare under P9603 for miles traveled by a laboratory technician to draw one or more samples from one or more Medicare beneficiaries who are either homebound or inpatients at inpatient facilities that are not hospitals"). Substantial evidence in the record supports that finding. That evidence includes three guidance documents that CMS and Trailblazer issued to Medicare participants and the public between May 2008 and August 2009.

On May 30, 2008, CMS published (on its website) Medicare Learning Matters (MLN) article MM5996, titled "Clinical Laboratory Fee Schedule – Medicare Travel Allowance Fees for Collection of Specimens." I.G. Ex. 13. This purpose of the article was to notify Medicare participants (and the public at large) about the recent changes to MCPM § 60.2 in Change Request 5996. Consistent with MCPM § 60.2, MM5996 specifies the minimum mileage rate "to cover the technician's time and travel costs"; states that contractors have the option of establishing a higher mileage rate if local conditions warrant; and notifies laboratories of their obligation to prorate the allowance "when one trip is made for multiple specimen collections." I.G. Ex. 13, at 2-3. MM5996 then states – in a separate one-sentence paragraph – that "[a]t no time will a laboratory be allowed to bill for more miles than are reasonable or for miles not actually traveled by the laboratory technician." *Id.* at 3. There is no indication in MM5996 that this prohibition applies only to some subset of per-mile travel-allowance claims.

On or about June 11, 2008, Trailblazer posted on its website a bulletin about CMS's May 30, 2008 Change Request (CR5996). I.G. Ex. 22. The bulletin advised Medicare participants in Trailblazer's jurisdiction (Texas) that the mileage rate that could be used to claim the per-mile travel allowance was the minimum rate established by CMS (then

 $<sup>^{8}\,</sup>$  The ALJ did not decide whether Petitioners had actual knowledge of the claims' falsity. ALJ Decision at 15 n.16.

\$0.955 per mile). *Id.* After noting that some Medicare contractors had elected to pay the travel allowance only on a flat-rate (per-trip) basis, the bulletin's concluding paragraph states: "At no time will a laboratory be allowed to bill . . . for miles not actually traveled by the laboratory technician." *Id.* Trailblazer's notice includes an internet link to MM5996, the MLN article about CMS's May 30, 2008 change request. *Id.* 

Finally, on August 9, 2009, twelve days before the start of the relevant period, CMS issued MLN article MM6524, which notified the public of revisions to the mileage and per-trip rates applicable to Part B travel-allowance claims. I.G. Ex. 12. That article, like the previous two, contains the same unqualified prohibition on billing for "miles not actually traveled by the laboratory technician." *Id.* at 2. We agree with the ALJ that this article and two previously mentioned guidance documents (MM5996 and Trailblazer's June 2008 bulletin) clearly advised Petitioners that they could not claim the per-mile travel allowance based on miles – air or ground – not traveled by trained personnel.

The ALJ's finding about Petitioners' knowledge is also supported by the testimony of Petitioners' own expert witness, Thomas Gustafson (a former CMS employee), who conceded that the prohibition on billing for "miles not actually traveled by the laboratory technician" - as it appeared in both CMS's May 30, 2008 MLN article (MM5996) and Trailblazer's June 2008 bulletin - was a "red flag" that obligated Petitioners to seek "clarification" from CMS or Trailblazer about the propriety of billing for miles that specimens were shipped after they had been collected by the phlebotomists and processed in BestCare's satellite facilities. Tr. at 448-56, 481-84. Petitioners did not seek or obtain such clarification during or prior to the relevant period. Although (as we recount in more detail below) Dr. Maghareh and BestCare's billing manager questioned a Trailblazer employee in July and November 2008 about billing for a specimen's flight mileage, they received no assurance from the employee that it would be proper to bill for such mileage when a laboratory technician did not fly with the specimen. The ALJ reasonably found in these circumstances that Petitioners deliberately ignored or recklessly disregarded information that should have made them aware that their billing for unaccompanied specimen shipment by air did not meet Medicare conditions for payment. Michael D. Dinkel, DAB No. 2445, at 6-8 (2012) (affirming an administrative law judge's finding that the owner of a diagnostic imaging laboratory "should have known" that Medicare claims that his laboratory submitted under a particular procedure code were false because the owner either ignored or failed to make a reasonable inquiry about coding definitions and guidelines which made it clear that claiming payment under the code was improper).

Petitioners make several points about the relevant evidence, but none persuades us that substantial evidence is lacking for the ALJ's finding about Petitioners' knowledge. For example, Petitioners submit that they did not "receive" the CMS and Trailblazer guidance documents prior to the relevant period and had "access" only to the Medicare Claims

Processing Manual and a 2002 version of Trailblazer's Laboratory and Pathology Manual. P. Br. at 12. Even if that statement is accurate (and it is not), the ALJ properly gave it no weight because Petitioners, as participants in the Medicare program, had a duty to acquaint themselves with the program's requirements for billing, coverage, and payment, a duty that further obligated them to consult reliable sources of information about those requirements (such as contractor bulletins and MLN articles). Heckler v. Cmty. Health Servs. of Crawford Cty., Inc., 467 U.S. 51, 63-64 (1984) ("As a participant in the Medicare program, respondent had a duty to familiarize itself with the legal requirements for cost reimbursement"); Gulf South Med. & Surgical Inst., DAB No. 2400, at 9 (2011). Furthermore, Petitioners do not contest the ALJ's finding that, during July 2008, Dr. Maghareh received and read Trailblazer's June 2008 bulletin, which advised laboratories that the travel-allowance claims would be paid at the minimum mileage rate, contained a link to the May 30, 2008 MLN article discussing the recent change request, and stated that a laboratory could "at no time" bill for miles not actually traveled by a laboratory technician. ALJ Decision at 19; I.G. Ex. 22; Tr. at 679-86, 714, 880-81, 887-89, 891-92.

Petitioners contend that CMS's and Trailblazer's guidance was "confusing and conflicting" and would not have put them on notice of any problem with their travelallowance claims.<sup>9</sup> P. Br. at 10. To the contrary, the three guidance documents published from May 2008 through August 2009 (the start of the relevant period) are clear and consistent: each states that a laboratory could "at no time" claim the per-mile travel allowance based on "miles not actually traveled by the laboratory technician." I.G. Exs. 12, 13, 22. Those were precisely the types of miles on which the travel-allowance claims in question were based.

During the hearing, Dr. Maghareh admitted that he reviewed Trailblazer's bulletin sometime in July 2008 and thought it to be "self-explanatory." Tr. at 892. When asked whether he thought that the bulletin's instruction not to bill for miles not actually traveled by a technician contradicted statements allegedly made to him by BestCare's billing manager that Trailblazer had approved billing for such miles, Dr. Maghareh replied that there was no contradiction but that he "always . . . want[ed] to get close to perfection and

<sup>&</sup>lt;sup>9</sup> In asserting that Medicare's guidance was confusing, Petitioners point to trivial and immaterial differences between some guidance documents as sources of potential confusion. P. Br. at 14. Petitioners also discuss at length pertinent sections of Trailblazer's Laboratory and Pathology Manual. *Id.* at 12-14. They assert that this manual "change[d] repeatedly [between 2002 and 2009] in manners inconsistent with" the MCPM. *Id.* at 14. However, Petitioners contend that they "only had access to the CMS Manuals and the 2002 Trailblazer manual (not the 2007 and 2009 Trailblazer manuals), and they deny they relied on the Trailblazer manual in deciding how to claim the per-mile travel allowance during the relevant period. *Id.* at 15. Moreover, Petitioners correctly note that CMS issued Change Request No. 5996 to the CMS Manual in June 2008 ("approximately a year before the Five-Month Period"), which contained the instruction not to bill for miles not actually traveled by the laboratory technician. *Id.* at 14 (citing I.G. Ex. 14).

make sure everything is clear." Tr. at 892-93. But the contradiction was obvious and should have been to Dr. Maghareh. As the individual ultimately responsible for ensuring that BestCare's billing was proper, Dr. Maghareh was obliged to resolve the contradiction before allowing his company to continue billing as it had (for air mileage not flown by trained personnel). He made no reasonable effort to do so, as our later discussion concerning his November 2008 conversation with a Trailblazer employee makes clear.

Petitioners point to testimony by Kari Ramirez, who became BestCare's billing manager in the summer of 2008. P. Br. at 11. Ramirez testified that, during the relevant period, Petitioners' travel-allowance claims reflected her interpretation of MCPM § 60.2 as permitting the billing of miles not traveled by a technician if those miles were billed at the "general minimum rate." P. Ex. 43, ¶¶ 14-16; Tr. at 597-604, 610-14. The implication here is that MCPM § 60.2 was ambiguous or unclear about the propriety of billing for miles not traveled by a technician (though Ramirez never said that she thought it to be (*see* P. Ex. 43, ¶¶ 11-17)), and that it was therefore reasonable for Petitioners to have billed in accordance with Ramirez's interpretation.

Although the ALJ found MCPM § 60.2 "not particularly ambiguous," he gave Petitioners the "benefit of the doubt" and found the MCPM "insufficiently clear, on its own, to definitively prohibit a laboratory from billing under the minimum per-mile travel allowance for samples unaccompanied by a laboratory technician." ALJ Decision at 17. We disagree. In our view, the interpretation posited by Ramirez is objectively unreasonable in light of the statutory language which it implements. It also conflicts with Trailblazer's June 2008 bulletin, which notified laboratories that the minimum mileage rate was applicable in Texas *and* that billing for miles not traveled by trained personnel was prohibited. Ramirez did not say how she reconciled her reading of MCPM § 60.2 with Trailblazer's June 2008 bulletin (a copy of which she received in July 2008). Nor did she say that she asked CMS or Trailblazer to verify that she had read MCPM § 60.2 correctly. Ramirez also admitted on cross-examination that she told no one – not even Dr. Maghareh – about her interpretation. Tr. at 611-12. Given these circumstances, Ramirez's alleged interpretation of MCPM § 60.2 does nothing to undercut the ALJ's finding that Petitioners recklessly disregarded the prohibition on billing for miles not traveled by a laboratory technician. Cf. United States ex rel. K & R Ltd. P'ship v. Mass. Hous. Fin. Agency, 530 F.3d 980, 983-84 (D.C. Cir. 2008) (holding, in a case brought under the False Claims Act, that a defendant does not recklessly disregard a claim's falsity if it submitted the claim with a "plausible" or "not unreasonable" understanding of a governing regulation).<sup>10</sup>

<sup>&</sup>lt;sup>10</sup> Judicial decisions in False Claims Act (FCA) cases may be instructive in section 1128(b)(7) exclusion cases because the FCA defines the terms "knowing" and "knowingly" and section 1128A defines the term "should know" to mean "deliberate ignorance" or "reckless disregard" of information's truth or falsity. 31 U.S.C. § 3729(b)(1); Act § 1128A(i)(7); *Dinkel* at 5 n.5.

Of course, if Petitioners actually thought that MCPM § 60.2 was unclear about whether BestCare could claim miles not traveled by trained personnel – and we see no contemporaneous evidence that they did despite their current claims – then they were obliged to seek authoritative guidance from CMS or Trailblazer about that section's intended meaning and "not simply 'take advantage of any perceived ambiguities . . . to file Medicare claims as [they] saw fit.'" *Dinkel* at 8 (quoting, with approval, a portion of the administrative law judge's analysis supporting the conclusion that the excluded individual acted with reckless disregard or deliberate ignorance of information). There is no evidence that Petitioners asked CMS or Trailblazer about any perceived ambiguity in MCPM § 60.2, and we accept the ALJ's factual findings that Petitioners did not receive advice from Trailblazer validating their practice as they claimed.

Petitioners contend that there was no reckless disregard or deliberate ignorance of Medicare billing rules because they claimed the travel allowance in accordance with guidance they received from a Trailblazer employee named Dean Richardson. P. Br. at 10, 15. This contention rests on evidence of two telephone conversations: a July 10, 2008 call between Kari Ramirez and Richardson; and a November 3, 2008 call between Dr. Maghareh and Richardson. The ALJ reviewed that evidence in detail but found that Richardson did not endorse or approve Petitioners' practice of billing air (and other) miles not traveled by a laboratory technician and that it was unreasonable for Petitioners to think that Richardson had done so. *Id.* at 21-26. We find no legal error or lack of substantial evidence for that finding.

Ramirez testified that "[t]o make sure we got things right, [BestCare employees] would call Trailblazer to figure out exactly what the program administrator thought was the right way to bill." P. Ex. 43, ¶ 18. During the summer of 2008, BestCare billing department employees called Trailblazer to "ask about whether [BestCare was] allowed to bill mileage under P9603 when specimens were flown to Houston as air cargo." Id., ¶ 34; see also I.G. Ex. 27. Ramirez testified that after two Trailblazer employees were unable to answer that question, she received a call from Richardson, a more senior and experienced ("Tier 3") employee, on July 10, 2008. P. Ex. 43, ¶ 38. Ramirez testified that she explained to Richardson during that call that BestCare was "flying specimens on planes from Dallas, San Antonio, El Paso, and other cities for testing in [its] Houston laboratory," and that she "asked him whether there was a problem with billing for travel allowance in that situation." Id. According to Ramirez, Richardson referred her to Trailblazer's June 2008 bulletin and then, after reading through that document, told her that "there [was] no rule that says we cannot charge for mileage to fly specimens." Id., ¶ 39. Ramirez testified that she handwrote Richardson's "instructions" on her paper copy of the Trailblazer bulletin and then:

I... confirmed these instructions with [Richardson] again. I specifically asked him whether we were allowed to bill for mileage associated with this air transportation. He said yes. Then, I told him again that no one from BestCare flew on the planes with the test tubes, BestCare personnel dropped the specimens off at the airport, and pick [sic] them up at the airport in Houston. Mr. Richardson again confirmed that yes, we were allowed to bill the mileage.

*Id.*,  $\P$  40.<sup>11</sup> Ramirez testified that she "followed Mr. Richardson's guidance" and his "interpretation" of Trailblazer's June 2008 notice. *Id.*,  $\P$  42.

In a sworn deposition given in connection with the parallel False Claims Act litigation, Richardson testified that he told Ramirez that the Medicare program's guidelines did not prohibit a laboratory from claiming air miles traveled to collect and return a specimen for testing, but that the guidelines "did require a technician to travel with [the specimen]" in order for those miles to qualify for the travel allowance. I.G. Ex. 33, at 46, 55, 57-58, 97. Richardson also testified that he did not recall whether or not Ramirez told him that a technician would not fly with the specimen, but "that I did tell her that it did require a technician to travel with it." *Id.* at 96-97.

By crediting Richardson's "recollection of the conversation," *see* ALJ Decision at 24, the ALJ effectively found that Richardson *did not* tell Ramirez that BestCare could claim the per-mile travel allowance based on air miles not flown by a technician. That finding is supported by Ramirez's contemporaneous notes of the call, which report only that Richardson said that it was "okay to charge for flight mileage," and do not state that it was proper to do so when the technician did not fly with the specimen. *See infra* footnote 11. The ALJ's finding is also supported by Richardson's telephone log of the July 10, 2008 call (I.G. Ex. 27), which states:

I spoke with Carrie [Ramirez] . . . on July 10, 2008. I informed her if the patient is not in a SNF, then the mileage code is set up for ground mileage. According to our Provider Education Specialist, we do not have any guidelines that state the specimen could not be collected and mileage not be

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States no guidelines stating you can't charge the mileage to fly specimens. So yes that is okay to charge for flight mileage.

<sup>&</sup>lt;sup>11</sup> Ramirez's handwritten notes at the bottom of her copy of Trailblazer's June 2008 bulletin read:

paid when traveling by air. The mileage code is however for ground mileage, not air. I cannot restrict her from billing for mileage *if the specimen and the technician are to travel by air* because this is not specifically addressed. I gave her the link to our Notices that give a link to the CMS transmittal and the MLN matters article . . . .

IG Ex. 27 (italics added). Nothing in this passage suggests that Richardson spoke with Ramirez about billing for air miles not traveled by the technician. To the contrary, it indicates that Richardson's advice was based explicitly on the assumption that a technician would be flying with the specimen. The telephone log also shows, as the ALJ aptly observed, that Richardson understood the issue posed by Ramirez as whether it was appropriate to bill for air miles traveled to *collect a sample* given that the mileage rate established by CMS covered costs of ground (automobile) transportation.

The Board generally defers to an ALJ's findings about witness credibility absent a "compelling" reason to do otherwise. *Dinkel* at 10. In addition, the Board does not disturb an ALJ's assignment of weight to different pieces of evidence if the ALJ gave rational reasons for the assignment. *Id.* at 11-12; *Thomas M. Horras*, DAB No. 2015, at 9 (2006) (noting that the Board does not "reweigh the evidence"), *aff'd*, *Horras v*. *Leavitt*, 495 F.3d 894 (8<sup>th</sup> Cir. 2007). Petitioners do not seek relief based on these review standards: they do not challenge any of the ALJ's credibility findings; nor do they argue that the ALJ did not rationally explain his refusal to accept key parts of Ramirez's testimony. They merely suggest that we accept their version of the July 10, 2008 conversation, as recalled by Ramirez. However, to do so would usurp the ALJ's authority and proper role to determine the weight and significance of conflicting evidence. We therefore do not disturb the ALJ's findings concerning the July 10, 2008 conversation between Ramirez and Richardson.

<sup>&</sup>lt;sup>12</sup> It is reasonable for a fact-finder to assign more weight to the contemporaneous record of an event than to a participant's distant recollection. *Jennifer Matthew Nursing & Rehab. Ctr.*, DAB No. 2192, at 52 (2008) (finding that the ALJ may reasonably give more weight to contemporaneous notes than to witness testimony); *Anderson v. Sullivan*, 925 F.2d 220, 222 (7<sup>th</sup> Cir. 1991) (ALJ could accord greater weight to contemporaneous evidence than to retrospective reports).

As for the November 3, 2008 telephone conversation between Dr. Maghareh and Richardson, a portion of it was recorded by Dr. Maghareh and transcribed. I.G. Ex. 31. The transcript in relevant part says:

KARIM MAGHAREH: You know the reason I want to do, I want to take advantage of this opportunity, if it exists, Mr. Dean, is again, we – we're processing at least 1,000 claim[s] a day, at least.

RICHARDSON: Yeah

KARIM MAGHAREH: And it's from all corners of the state. We have too many driving around [UNINTEL]. And I think you may remember, if I give you this reference number . . . 57662 [corresponding to Richardson's July 10, 2008 call with Ramirez] . . .

RICHARDSON: Mm hmm. I've got Carrie -

KARIM MAGHAREH: Yeah.

\* \* \*

RICHARDSON: Well, I basically told her that the patient is not – that if the patient is not in a skilled nursing facility where the mileage code is set up for ground mileage –

KARIM MAGHAREH: Mm hmm.

RICHARDSON: -- in other words, there, -- she was wanting to fly.

KARIM MAGHAREH: Their specimens?

RICHARDSON: They're wanting air mileage, but the code is not set up for air mileage it's ground mileage. You basically had to determine what the ground mileage would be and that's what your reimbursement would've been.

KARIM MAGHAREH: I see. So, we could go ahead and – as I was told by Carrie, that yes, it's okay to figure the ground mileage and then use it for the specimen flying?

RICHARDSON: Right.

KARIM MAGHAREH: I see . . . they just have to figure out ground mileage from BestCare Houston to the other place and then use that mileage?

RICHARSON: That's right.

KARIM MAGHAREH: Okay. And just fly the specimen itself?

RICHARSON: Right.

I.G. Ex. 31, at 6-7. Petitioners attribute great significance to Richardson's affirmative response to Dr. Maghareh's cryptic question, "And just fly the specimen itself?" P. Br. at 3, 19. We agree with the ALJ that this is a "flimsy reed indeed upon which to rest millions of dollars' worth of billing to the government." ALJ Decision at 25. As the ALJ noted, "upon hearing this recording [of the November 3, 2008 telephone call], Mr. Richardson made it clear [in his deposition] that he understood the situation posed by Dr. Maghareh to describe air travel by technicians bearing samples." *Id.* (citing I.G. Ex. 33, at 98-105). The ALJ also noted that Mr. Richardson "felt strongly enough about this issue that he annotated the contemporaneous record of his interaction with BestCare to clarify that Dr. Maghareh implied the specimens referenced in their conversation traveled accompanied by technicians and that he was cut off by Dr. Maghareh before he could restate the advice he provided Kari Ramirez, which would have clearly informed him mileage reimbursement was intended only for a sample traveling with a technician." *Id.* (citing I.G. Ex. 27, at 2)

It is also important to note that rather than rely on one cryptic statement and response, the ALJ examined the entire transcript of Dr. Maghareh's conversation with Richardson and found that it could not be "reasonably construed" as "permitting BestCare to use the P9603 code to bill for miles traveled by a specimen unaccompanied by a technician." ALJ Decision at 24. That finding is sound: nothing in the transcript even hints that Richardson understood that BestCare wanted to claim the travel allowance based on such miles or that he advised Dr. Maghareh that it was proper to do so. If anything, the transcript reinforces the impression conveyed by Richardson's log of the July 10, 2008 call (and by Dr. Maghareh's own direct testimony (*see* P. Ex. 42, ¶ 39)) that BestCare aimed merely to confirm that it could claim a travel allowance for air mileage based on a calculation of ground distance between specimen-collection points and its Webster lab.<sup>13</sup> The transcript also shows no inquiry by Dr. Maghareh about whether billing for

<sup>&</sup>lt;sup>13</sup> According to Dr. Maghareh, Richardson advised him that "if a patient was in a facility where the mileage code for billing purposes was set up for ground mileage, but the specimen was flown, that it was appropriate to determine what the ground mileage would be and use that mileage figure for reimbursement." P. Ex. 42, ¶ 39.

specimen-only flight mileage might run afoul of the instruction not to bill for "miles not actually traveled by the laboratory technician." Had Dr. Maghareh been interested in knowing whether BestCare's practice of billing air mileage complied with Medicare requirements, he could have asked a simple direct question (one that should have occurred to him after reading Trailblazer's June 2008 bulletin): could BestCare bill for a specimen's flight mileage if no laboratory technician flew with the specimen?

Petitioners submit that it is "irrelevant" for purposes of the "reckless disregard" element that Richardson did not understand that BestCare wanted to bill for miles not traveled by a laboratory technician. P. Br. at 19. "What is relevant," say Petitioners, is "how Dr. Maghareh . . . interpreted [his] conversation" with Richardson. *Id.* We disagree. It is not enough for Dr. Maghareh to have subjectively believed (assuming he did) that Richardson had given him the green light to bill for miles not traveled by trained personnel. Such a belief had to be *objectively* reasonable. *Cf. United States v. Krizek*, 111 F.3d 934, 942 (D.C. Cir. 1997) (holding that reckless disregard "may be established without reference to the subjective intent of the defendant"). It was unreasonable for Dr. Maghareh to think that Richardson had advised him about the propriety of billing for air miles not traveled by a technician when that subject was never explicitly raised or even discussed.<sup>14</sup>

Petitioners contend they had reason to believe that billing for air miles not traveled by trained personnel was permissible in light of "advice" they purportedly received from a private billing consultant (Medigain) and the results of audits performed by two Medicare contractors (TriCenturian and CERT DC). P. Br. at 15-16, 19-20, 32. The ALJ rejected that proposition because "none of [those] outside parties were fully confronted with the exact issue of how Petitioners billed travel." ALJ Decision at 22. Petitioners do not call that finding into question: they cite no evidence that the consultant and Medicare auditors even knew about, much less endorsed or approved, Petitioners' practice of billing for miles that laboratory technicians did not travel.

<sup>&</sup>lt;sup>14</sup> Dr. Maghareh testified that in discussing air mileage with Richardson, he "made clear" that a specimen would be "flying by itself" and that he "described [to Richardson] the process that BestCare followed of collecting the specimen from the patient, taking it to a lab for initial processing, then taking it [to] the airport for cargo shipment to the lab in Webster without a phlebotomist, and finally picking it up at the airport in Houston to bring to the Webster lab." P. Ex. 42, ¶ 39. But these statements are not corroborated by the transcript of the November 3, 2008 call, and Petitioners do not cite them or contend that they are material to our review under the substantial evidence standard.

Finally, Petitioners contend that a district court's decision in *United States ex rel. Saldivar v. Fresenius Med. Care Holdings, Inc.*, 145 F. Supp. 3d 1220 (N.D. Ga., Oct. 30, 2015) is instructive.<sup>15</sup> *Fresenius* concerned Medicare claims submitted by a dialysis provider (the defendant) seeking payment for the administration of drug "overfill" – which is the amount of drug in a vial that exceeds the amount indicated on the vial's label or packaging. The plaintiff alleged that those claims violated the False Claims Act because they were false and the defendant knew or should have known of their falsity. The defendant moved for summary judgment, contending it did not submit the claims with actual knowledge, deliberate ignorance, or reckless disregard of their falsity.

The district court granted the defendant's motion, concluding that although there was some evidence that the defendant "had the necessary information at its disposal to deduce that billing for overfill was impermissible, there [was] no evidence that [the defendant] actually knew that billing for administered overfill was impermissible, and insufficient evidence from which a reasonable jury could find [that the defendant] acted with deliberate ignorance or reckless disregard as to the impermissibility of billing for administered overfill." 145 F. Supp. 3d at 1222. The court cited various factors supporting its conclusion that the defendant did not act with deliberate ignorance or reckless disregard. Most notably, the court found that relevant Medicare rules and regulations were "not simply ambiguous" about billing for administered overfill but were "silent." Id. at 1255, 1260 (further stating that it was "undisputed that no rule or regulation expressly prohibited billing for administered overfill until" after the relevant claims had been submitted). In addition, neither CMS nor its contractor had adopted policies or issued guidance addressing whether the administration of overfill was reimbursable. Id. at 1264-65. The court also held that the defendant reasonably believed that the billing for administered overfill was permissible based on the advice of its lawyers, its "long history" of such billing, the "apparent widespread industry practice of overfill billing," and its disclosure of the practice to the government. Id. at 1260-61. Finally, the court noted that there was some evidence that the defendant took its responsibility to submit valid claims seriously by, for example, meeting with CMS and consulting with attorneys to clarify Medicare requirements and procedures. Id. at 1266 n.40.

The circumstances that led the district court in *Fresenius* to reject the plaintiff's False Claims Act claim in *Fresenius* are missing here. In this case, governing Medicare law was not silent about the propriety of Petitioners' practice of claiming the travel allowance for air and ground mileage not traveled by a technician; to the contrary, the statute itself alerted Petitioners that the practice was highly suspect, if not explicitly barred. There was also no lack of applicable written program guidance and policy – all of which told Petitioners that billing for miles not actually traveled by a technician was prohibited.

<sup>&</sup>lt;sup>15</sup> The district court's decision in *Fresenius* was reversed on appeal for want of subject matter jurisdiction. *United States ex rel. Saldivar v. Fresenius Med. Care Holdings, Inc.*, 841 F.3d 927 (11th Cir. 2016).

Assuming that Petitioners were confused or uncertain about the rules, they did not (unlike the defendant in *Fresenius*) seek legal advice to ensure that they complied with them. In addition, as the record of Petitioners' conversations with Dean Richardson illustrates, Petitioners were far from transparent with Medicare about the nature of the air miles they wanted to bill or were already billing. Finally, there is no evidence that Petitioners' problematic billing conformed to "industry practice." Thus, *Fresenius* in no way undercuts the ALJ's conclusion that Petitioners billed Medicare with reckless disregard or deliberate ignorance of the applicable rules.<sup>16</sup>

Because substantial evidence supports the ALJ's finding that Petitioners deliberately ignored or recklessly disregarded Medicare's prohibition on billing for miles not traveled by trained personnel, we affirm his conclusion that Petitioners should have known that 571 travel-allowance claims that they submitted during the relevant period based on such miles were false.

# C. The ALJ committed no error in concluding that 15 years is a reasonable period of exclusion.

We next consider the ALJ's conclusion that the length of the proposed exclusion -15 years – was reasonable. Title 42 C.F.R. § 1001.901(b) states that in determining the length of an exclusion that is based on acts described in section 1128A of the Act, the I.G. "will consider the following factors":

- (1) The nature and circumstances surrounding the actions that are the basis for liability, including the period of time over which the acts occurred, the number of acts, whether there is evidence of a pattern and the amount claimed;
- (2) The degree of culpability;
- (3) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing (The lack of any prior record is to be considered neutral);
- (4) The individual or entity has been the subject of any other adverse action by any Federal, State or local government agency or board, if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion; or

<sup>&</sup>lt;sup>16</sup> Even if the many distinguishing circumstances we note between the two cases were absent, *Fresenius* would not be dispositive or even necessarily instructive for purposes of our decision. *Fresenius* is a decision by one federal district court judge and was reversed on appeal, albeit for jurisdictional reasons. In addition, a judge's determinations of knowledge and intent are based on the specific facts before the judge in a particular case, and, as previously stated, we give substantial deference to this ALJ's findings of fact on the record before him.

(5) Other matters as justice may require.

In reviewing an exclusion's length, an ALJ "may not substitute his judgment for that of the I.G.," which has "broad discretion" in establishing an appropriate exclusion period. *Dinkel* at 19. Instead, an ALJ must determine whether the exclusion period chosen by the I.G. was "within a reasonable range, based on demonstrated criteria." *Id.* In this case, the "demonstrated criteria" are the factors outlined in section 1001.901(b) of the I.G.'s regulations.

In their post-hearing brief to the ALJ, Petitioners argued that consideration of those factors justified an exclusion shorter than 15 years. P.'s June 18, 2018 Post-Hearing Br. at 23-28. The ALJ disagreed, finding that 15 years was reasonable based on the first three regulatory factors (in paragraphs (1), (2), and (3) of section 1001.901(b)). ALJ Decision at 29-32. Regarding the first factor – the "nature and circumstances surrounding the actions that are the basis for liability" – the ALJ found that, during the relevant period, Petitioners engaged in a "pattern" of improper billing in which they "repeatedly used a billing code [P9603] intended to reimburse for travel by a technician to request payment for hundreds of miles of air travel where samples were simply shipped from locations all over Texas to BestCare's central laboratory without a technician." *Id.* at 29. The ALJ estimated that Petitioners' improper billing during the relevant period resulted in a "significant" loss to the federal government – \$228,000 – in a "relatively short period of time." *Id.* 

Regarding the second factor (degree of culpability), the ALJ found the Petitioners to be "highly culpable" in submitting the false claims. *Id.* at 30. Their actions, the ALJ said, "were not merely negligent" and were either "by design" or in "reckless disregard for the law as it pertained to an obvious limitation against their billing practices." *Id.* In addition, the ALJ found that, as of 2009, BestCare's travel-allowance claims based on miles that specimens flew as air cargo accounted for a substantial portion of its annual Medicare revenue, implying that Dr. Maghareh, who received large distributions from the company as its majority owner, ignored an inconvenient rule (the prohibition on billing for miles not actually traveled by a technician) in order to preserve a lucrative income stream. *Id.* 

As for the third factor – "documented history of criminal, civil or administrative wrongdoing" – the ALJ found that the District Court's grant of partial summary judgment to the United States in the parallel qui tam lawsuit, coupled with the court's related finding that the United States was entitled to recoup \$10.6 million from Petitioners, established that Petitioners had a "documented history of criminal, civil or administrative wrongdoing" – namely, "improper billing practices with respect to [HCPCS] Code

P9603" – that predated the relevant period, beginning as early as 2004. *Id.* at 30-31. The ALJ went on to say that even if he overlooked this factor, his conclusion that a 15-year exclusion is reasonable would not change because the "egregious nature and circumstances of Petitioners' conduct, coupled with their high degree of culpability," demonstrated that they were profoundly untrustworthy. *Id.* at 31.

In response to the ALJ's findings regarding the first regulatory factor (in paragraph (1) of section 1001.901(b)), Petitioners assert that the I.G.'s case "covers 571 out of 69,017 (0.8%) P9603 claims, submitted during a five-month time period out of BestCare's sixteen years of operation"; that "the I.G.'s own witness had to admit that the I.G. could not put forth any analysis to show a 'pattern' of false claims"; and that "[t]he evidence, at most, shows a minute fraction of P9603 claims BestCare submitted in error." P. Br. at 26 (citing Tr. at 380). These points reveal no error by the ALJ. To begin with, the number of actual false claims from the relevant period was certainly higher than 571. Petitioners take no issue with the ALJ's statement (ALJ Decision at 30) that the 571 claims at issue were only a subset of false claims from the relevant period and merely the "most egregious in terms of loss to the government." Second, the record does not substantiate Petitioners' implication that only 0.8 percent of BestCare's per-mile travel-allowance claims across its entire 16-year existence were false or improper, and this claim lacks credibility on its face given the evidence that Petitioners were billing for air miles not traveled by a technician for at least one year prior to the relevant period (August 2008 to August 2009) and after having received Trailblazer's June 2008 bulletin instructing laboratories not to bill for such miles. P. Ex. 42, ¶ 30; P. Ex. 43, ¶¶ 35, 45-48; Tr. at 634-38, 643-46, 679-85, 714, 810; I.G. Ex. 3, at 167-70. The implication is also irrelevant under section 1001.901(b)(1), which directs the I.G. to consider, not the percentage of improper claims submitted across all years of operation, but the "number of acts" (claims) resulting in liability and the "circumstances surrounding" those acts circumstances which do not include the fact that Petitioners may have properly billed Medicare after authorities discovered their false claims. More important, even if BestCare's false claims constituted a small percentage of its total Medicare billings during and prior to the relevant period, that fact does not negate the ALJ's finding that Petitioners engaged in a "pattern" of improper claiming. In this context, the word "pattern" can mean "something that happens in a regular and repeated" way, as distinct from events that occur sporadically or accidently. See definition of pattern in Merriam-Webster's Online Dictionary (https://www.merriam-webster.com/dictionary/pattern); Access Foot Care, Inc., DAB No. 2752, at 11-12 (2016). That definition describes what occurred here: contrary to clearly stated guidance and instructions, Petitioners regularly and repeatedly claimed the per-mile travel allowance based on miles not traveled by trained personnel. Such claiming was no accident. Dr. Maghareh admitted that it was BestCare's practice to bill Medicare in this way, by including on a travel-allowance claim a "mileage charge" with respect to any specimen that had been shipped by air from a Texas location (other than the Houston metropolitan area) to its Webster lab for testing. P. Ex. 42, ¶ 30. The ALJ therefore justifiably found that Petitioners had engaged in a "pattern" of false claiming during the relevant period. *Cf. Access Foot Care, Inc.* at 13 (holding that a Medicare supplier's submission of 13 improper Medicare claims over the course of seven months constituted a "pattern" of improper billing that subjected the supplier to revocation of its Medicare billing privileges).<sup>17</sup>

Turning to the ALJ's culpability finding (under section 1001.901(b)(2)), Petitioners assert that "[e]very witness who had knowledge of BestCare's billing, including the I.G.'s own witness [referring to Leigh Del Rio, a former BestCare employee], testified that BestCare always billed the 'right way." P. Br. at 26 (quoting Tr. at 124)). This statement is essentially a *denial* of any culpability, which cannot be squared with the ALJ's finding, which we have concluded is supported by the record, that Petitioners acted in reckless disregard or deliberate ignorance of Medicare rules. Furthermore, the I.G.'s witness, Ms. Del Rio, a BestCare employee from April 2006 until approximately May 2008, did not testify that Petitioners always billed the right way, only that BestCare employees "wanted" to do it "the right way." Tr. at 124. In her written direct testimony, Ms. Del. Rio described feeling uncomfortable with how billing was done in a number of respects but feeling that Dr. Maghareh was not concerned or told her to continue billing the same way when she talked to him. See I.G. Ex. 24, ¶¶ 5-10. Del Rio, whom the ALJ found credible (ALJ Decision at 12 n.14), also testified that she had been instructed by Dr. Maghareh on one occasion to continue billing for miles flown by specimens even after she told him that a technician informed her that those specimens were no longer being flown to another city, and that she refused to do so. See id, ¶ 5; Tr. at 332-35 (discussing billing for miles between BestCare's local laboratories and the Webster lab even though specimens for which the miles were billed were tested in the local laboratory and not flown to Houston). That Del Rio declined to follow this unlawful instruction obviously does not exonerate the giver of the unlawful instruction. In short, Petitioners give us no reason to question the ALJ's finding that Petitioner's culpability was "high" and warrants a lengthy exclusion. Cf. Dinkel at 22 (affirming an administrative law judgment's finding that a diagnostic imaging center owner's "reckless disregard . . . indicated high culpability and untrustworthiness").

Petitioners next contend that the ALJ improperly relied on the District Court's judgment in the parallel qui tam case to find, under section 1001.901(b)(3), that they had a "documented history of criminal, civil or administrative wrongdoing" relating to their Medicare claiming practices. P. Br. at 27-28, 29-32. Petitioners argue that such reliance

<sup>&</sup>lt;sup>17</sup> Petitioners do not question the ALJ's other key finding associated with the first regulatory factor, which is that the 571 false claims identified by the I.G. resulted in a "significant" financial loss to Medicare in a "relatively short period of time."

was improper because the judgment was not "based on the same set of circumstances that serves as the basis for the imposition of the exclusion." *Id.* at 27 (internal quotation marks omitted). That argument does not help Petitioners. Section 1001.901(b)(3) does *not* require that a "documented history" of wrongdoing be "based on the same set of circumstances that serves as the basis for the imposition of the exclusion." That condition appears only in section 1001.901(b)(4), which requires the I.G. to consider whether the person subject to exclusion "has been the subject of any other *adverse action* by any Federal, State or local government agency or board, *if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion*" (italics added). The ALJ expressly declined to find that Petitioners had been the subject of another "adverse action" within the meaning of section 1001.901(b)(4). ALJ Decision at 31.

Petitioners contend that the judgment in the parallel judicial proceeding "should not have influenced this exclusion decision" because the District Court did not hold a trial (the case having been decided on motions for summary judgment) and because they are presently appealing the judgment. We need not consider that contention because the ALJ found that the first two regulatory factors would support a fifteen-year exclusion even if the ALJ did not consider the third regulatory factor. ALJ Decision at 31. *See supra* at 24.

Under the heading of "other matters" that must be considered in the interest of "justice" (the factor specified in section 1001.901(b)(5)), Petitioners contend (as they did before the ALJ) that the Medicare program "needs no protection" from them, and that an exclusion in their circumstances is "purely punitive" and "contradicts the purpose of the exclusion statute and threatens to harm patient care." P. Br. at 27. The ALJ rejected these contentions, ALJ Decision at 32, and so do we. Petitioners cite no evidence that they can be trusted to bill Medicare in accordance with program requirements. *See* P. Br. at 28. In addition, the ALJ correctly noted, *id.*, that Petitioners offered little more than speculation that the exclusion would "harm patient care," and we doubt that such evidence would outweigh the manifest financial risk to the program from Petitioners' participation. Their contention that the exclusion is a punitive sanction is legally meritless, as "it is well-established that section 1128 exclusions are remedial in nature, rather than punitive, and are intended to protect federally-funded health care programs from untrustworthy individuals." *Dinkel* at 19.

Finally, Petitioners assert that "other [exclusion] actions by the Inspector General [resulting in decisions by administrative law judges or the Board] have demonstrated that far less severe exclusion periods are appropriate for individuals who were involved in more culpable conduct." P. Br. at 28-29 (citing decisions). A lengthy exclusion, Petitioners say, "is more commonly associated with felony convictions *than with billing errors.*" *Id.* at 28 (italics added). However, the Board has repeatedly held that "comparisons with other cases are not controlling and of limited utility given that

exclusion factors must be evaluated based on the circumstances of a particular case . . ., which can vary widely."<sup>18</sup> *Dinkel* at 22 (internal quotation marks omitted). Furthermore, Petitioners' suggestion that a 15-year exclusion is comparatively excessive rests upon a mischaracterization of the wrongdoing found by the ALJ. Contrary to what Petitioners imply, the ALJ did not find that they had committed inadvertent, accidental, or innocent "billing errors" or submitted improper claims based on a reasonable and honest misunderstanding of Medicare requirements. Rather, over the course of several months, they submitted hundreds of Medicare claims in reckless disregard or deliberate ignorance of their falsity.

In short, Petitioners have not identified any material error by the ALJ in assessing the relevant regulatory factors. Nor have they shown that the I.G. abused its "broad discretion" (*Dinkel* at 19) in setting the length of the exclusion based on those factors.<sup>19</sup> We therefore decline to disturb the ALJ's conclusion that 15 years is a reasonable period of exclusion under the circumstances.

#### D. The Board will not consider Petitioners' "Objections to ALJ Thomas' Authority" or their request for discovery regarding the circumstances of the ALJ's appointment.

In *Lucia v. SEC*, 138 S. Ct. 2044 (2018), the Supreme Court held that administrative law judges of the Securities and Exchange Commission are "inferior Officers" of the United States (and not simply federal government employees) who, as provided in the Constitution's Appointments Clause (Art. II, § 2, cl. 2), must be appointed by the President, a court of law, or the head of a department. 138 S. Ct. 2044 (2018). The Court also held that the "appropriate remedy for an adjudication tainted with an appointments violation is a new hearing before a properly appointed official." *Id.* at 2055 (internal quotation marks omitted).

Relying on *Lucia*, Petitioners state "Objections to ALJ Thomas' Authority" based on what they term "a good faith basis to believe" that the ALJ who decided their exclusion case (Judge Thomas) was unconstitutionally appointed. P. Br. at 34. Petitioners request "narrow, targeted discovery . . . to verify" that good-faith belief and state that if

<sup>&</sup>lt;sup>18</sup> Although the Board has said that "case-to-case comparisons can inform whether a period of exclusion falls within a reasonable range," *Andrew Louis Barrett*, DAB No. 2887, at 8 (2018) (internal quotation marks omitted), Petitioners have made only superficial comparisons between cases, failing to account for all the relevant "demonstrated criteria" at play in each case.

<sup>&</sup>lt;sup>19</sup> Despite the ALJ's reasoning that his "inquiry *must at least* consider how these other matters would tend to reflect upon Petitioners' trustworthiness" (ALJ Decision at 32 (italics added)), "general trustworthiness" is not "an independent basis, i.e., independent from the specified aggravating and mitigating factors, for determining whether the period of an exclusion is unreasonable." *Angelo D. Calabrese, M.D.*, DAB No. 2744, at 6 (2016) (and cases cited therein) (internal quotation marks and brackets omitted).

"discovery reveal[s] that ALJ Thomas was not appointed to his position by the President or by the HHS Secretary, his appointment and his Decision in this case would be constitutionally invalid under *Lucia*, and [they] would request a new hearing on the merits, as is required under these circumstances, in front of a different, properlyappointed ALJ." *Id.* at 34.

The regulations that govern Board appeals in section 1128 exclusion cases (42 C.F.R. §§ 1005.21-1005.23) do not provide for discovery at this level, but only for remand, stating if a party demonstrates that additional relevant evidence was not presented to the ALJ and reasonable grounds are shown "for the failure to adduce such evidence at such hearing, the DAB may remand the matter to the ALJ for consideration of such additional evidence." 42 C.F.R. § 1005.21(f). Those regulations also provide that the Board "will not consider . . . any issue in the [parties' appeal] briefs that could have been raised before the ALJ but was not." 42 C.F.R. § 1005.21(e). ALJs and the Board are bound by all applicable regulations. *Kenneth Schrager*, DAB No. 2366, at 6 (2011).

The ALJ proceeding concerning Petitioners' exclusion spanned 34 months, from October 2015 through August 2018. During that time, Petitioners did not question the validity of either presiding ALJ's appointment or make a related discovery request. Petitioners could have done so, however, for the following reasons.

First, by the end of 2016, approximately fifteen months before ALJ Thomas commenced the in-person evidentiary hearing, Petitioners had reason to know that the ALJ's authority might be open to challenge under the Appointments Clause because on December 27, 2016, the Tenth Circuit held in Bandimere v. SEC, 844 F.3d 1168, 1188 (10th Cir. 2016) that SEC administrative law judges are inferior officers. Second, irrespective of Bandimere, Petitioners could have questioned the constitutionality of the ALJ's appointment at any point during the adjudication based on the Supreme Court's 1991 decision in *Freytag v. Commissioner*, (501 U.S. 868), whose analysis the Supreme Court in Lucia and the Tenth Circuit in Bandimere found dispositive. See 138 S. Ct. at 2047, 2053 (stating that *Freytag* "sa[id] everything necessary to decide this case"); *Bandimere*, 844 F.3d at 1174 (stating that Freytag "provides the guidance needed to decide this appeal"). Third, Petitioners could have raised the Appointments Clause issue before the ALJ after the Supreme Court handed down Lucia. The Supreme Court issued Lucia on June 21, 2018, three days after the parties submitted their post-hearing briefs and 57 days before the ALJ issued his decision. Petitioners suggest that the ALJ's April 19, 2018 order setting the post-hearing briefing schedule "did not allow" any post-hearing submissions besides the post-hearing briefs. Petitioners' Reply Brief (Reply) at 3. While that order advised the parties that they could not respond to each other's post-hearing briefs, the order did not say that the record would be closed to all further submissions

once those briefs were filed. Nor did the order state that the ALJ would under no circumstances consider a legal matter or development that a party believed to have arisen or occurred after the post-hearing briefs were filed. In addition, no regulation or Civil Remedies Division procedure prohibited Petitioners from attempting to raise the Appointments Clause issue at the post-hearing stage.

Because Petitioners could have raised the Appointments Clause issue before the ALJ but did not, we will not, in accordance with 42 C.F.R. § 1005.21(a), consider that issue, and for that reason we deny Petitioner's request for discovery because it seeks information that is immaterial to the outcome of this proceeding at this stage.

#### Conclusion

For the reasons stated above, we affirm the ALJ's decision to exclude Petitioners from federal health programs for 15 years.

/s/

Leslie A. Sussan

/<u>s</u>/

Christopher S. Randolph Presiding Board Member