Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Karim Maghareh, Ph.D.

and

BestCare Laboratory Services, LLC,

Petitioners,

v.

The Inspector General.

Docket No. C-16-40

Decision No. CR5166

Date: August 17, 2018

DECISION

Petitioners, Karim Maghareh, Ph.D. and BestCare Laboratory Services, LLC, are excluded from participation in Medicare, Medicaid, and all other federal health care programs for a period of 15 years. As explained below, Petitioners presented or caused to be presented claims for Medicare items or services that they should have known were false or not provided as intended. A 15-year exclusion period is reasonable.

I. Procedural History

By letter dated August 21, 2015, the Inspector General of the United States Department of Health and Human Services (the I.G.) proposed to exclude Petitioners from participation in Medicare, Medicaid, and all federal health programs under section 1128(b)(7) of the Social Security Act (Act) (42 U.S.C. § 1320a-7(b)(7)) for a period of 15 years. The I.G. explained he proposed this action based on Petitioners' submission of claims to Medicare from August 2009 to January 2010 that Petitioners knew or should

have known were not provided as claimed and were false or fraudulent. Petitioners' (P.) Request for Hearing (RFH), Ex. A at 2.[1]

On October 19, 2015, Petitioners timely requested a hearing before an administrative law judge, and Administrative Law Judge Scott Anderson was designated to hear and decide this case. Judge Anderson held a pre-hearing conference on December 2, 2015, the substance of which is summarized in his December 3, 2015 Order Following Prehearing Conference and Schedule for Discovery (Prehearing Order). Judge Anderson set a schedule for discovery as permitted by the governing regulations. Prehearing Order at 3; 42 C.F.R. § 1005.7.

On March 8, 2016, Petitioners moved to extend the discovery deadlines and stay this matter pending resolution of a parallel proceeding in the U.S. District Court for the Southern District of Texas, *Drummond ex rel. United States of America v. BestCare Laboratory Services, LLC, et al.*, No. 08-02441 (District Court Case). The I.G. opposed the stay request, which Judge Anderson denied on March 23, 2016. He did however twice extend the discovery schedule at Petitioners' request.

On May 23, 2016, Petitioners moved to compel the I.G. to produce certain documents or, in the alternative, that subpoenas be issued for the production of those documents by witnesses at the hearing. Judge Anderson denied their motion on September 20, 2016.

In a separate order also dated September 20, 2016, Judge Anderson set a schedule for the parties to submit prehearing exchanges consisting of documentary evidence and arguments, which also identified proposed witnesses. He also set this matter for hearing beginning February 7, 2017. At Petitioners' behest, Judge Anderson rescheduled the hearing to take place beginning February 27, 2017.

On October 28, 2016, the I.G. filed a motion for summary judgment with a supporting brief, a pre-hearing brief (I.G. Pre-hearing Br.), an exhibit list, a witness list that included five proposed witnesses, five attachments (I.G. Attachments A-E), and 32 exhibits (I.G. Exs. 1-32), including the written direct testimony of three[2] proposed witnesses. On December 5, 2016, Petitioners filed a cross-motion for summary judgment with a supporting brief and an exhibit, a pre-hearing brief (P. Pre-hearing Br.), an exhibit list, a witness list with four proposed witnesses, and 34 exhibits (P. Exs. 1-34) including the

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[1] Document 1a in the official case file maintained in the DAB E-File system; for clarity and simplicity, whenever possible I will cite to the exhibits attached to the parties' respective briefs by the exhibit numbers therein, not the document numbers assigned by the E-file system.

[2] The I.G. had moved on October 12, 2016 to treat its two other proposed witnesses as adverse, with direct testimony to be elicited at the hearing. However, Petitioners ultimately submitted declarations from these two witnesses, and both were subject to cross-examination by the I.G. at the hearing I held in this matter, rendering the I.G.'s motion moot.

written direct testimony of all four proposed witnesses. In that pleading, Petitioners also objected to several of the I.G.'s exhibits and attachments and requested to cross-examine the I.G.'s proposed witnesses. On December 19, 2016, the I.G. filed a response to Petitioners' motion for summary judgment, a reply to Petitioners' response to the I.G.'s summary judgment motion, a pre-hearing reply brief, and objections to several of Petitioners' proposed exhibits and witnesses. The I.G. also requested cross-examination of Petitioners' witnesses, responded to Petitioners' objections, and filed an additional exhibit (I.G. Ex. 33) with an updated exhibit list. On January 9, 2017, with Judge Anderson's leave, Petitioners filed a short sur-reply to the I.G.'s replies with two attachments and also responded to the I.G's objections to their proposed witnesses.

In January 2017, the parties sought subpoenas for the production of certain witnesses and documents at the hearing. The I.G. also filed an opposition to Petitioners' subpoena requests, with five attachments, on January 23, 2017. Judge Anderson deferred ruling on these matters for the reasons outlined in Petitioners' February 1, 2017 Emergency Unopposed Motion for Continuance to Reset Hearing, and cancelled the hearing set to begin February 27, 2017.

On June 27, 2017, I was designated to hear and decide this case due to Judge Anderson's unavailability. After reviewing the record, I issued an Omnibus Order on October 6, 2017, in which I addressed the issues and motions still pending, including the parties' cross-motions for summary judgment, the motion to reset the hearing, the parties' cross-objections, and the parties' outstanding subpoena requests.[3] I also scheduled a pre-hearing conference to discuss rescheduling the hearing.

I held that pre-hearing conference on November 2, 2017, the substance of which was summarized in my November 7, 2017 order. After consulting counsel for the parties, I set this matter for a hearing to take place beginning March 26, 2018.[4] Regarding the I.G.'s two proposed adverse witnesses, I offered Petitioners the opportunity to submit written direct testimony for those witnesses, who would then be subjected only to cross-examination by the I.G.; Petitioners subsequently submitted affidavits from both witnesses, one of which included additional attachments. The I.G. did not object to testimony from either witness but did object to the additional documents. On January 12,

[3] In the Omnibus Order, I sustained the I.G.'s objection to P. Ex. 30 on the grounds that it was incomplete and gave Petitioners the opportunity to file an amended version of P. Ex. 30 that contained a complete version of the document of which Petitioners originally sought to include only an excerpt. Petitioners did re-file P. Ex. 30. However, as discussed more fully below, I subsequently excluded this exhibit altogether for reasons unrelated to the I.G.'s objection. Transcript (Tr.) at 17.

[4] During the conference, I advised the parties to jointly indicate whether they wished for an in-person hearing or to proceed by video hearing. They subsequently agreed to appear before me in person at the Departmental Appeals Board's offices in Washington, D.C.

2018, I provisionally admitted the testimony of these two witnesses, but struck the additional documents Petitioners attached.

Petitioners later re-filed those additional documents and witness testimony and submitted several additional documents as separate exhibits, labeled P. Exs. 35-43. The I.G. objected to P. Exs. 37-41. On March 8, 2018, at the parties' request, I held a second pre-hearing conference. During that conference, I overruled the I.G.'s objections and admitted P. Exs. 35-41 into the record.[5] The I.G. also gave notice that it would not be producing one of its witnesses, whose testimony was submitted as I.G. Ex. 23, at the hearing. Based on this representation, I informed the parties that I would not admit I.G. Ex. 23 into the record and would determine the admissibility of P. Ex. 30, a transcript of a deposition of the I.G.'s witness, at the hearing. Finally, the I.G. expressed its wish to call two rebuttal witnesses. I directed the I.G. to file a motion to that effect and gave Petitioners an opportunity to respond prior to the hearing.

On March 13, 2018, the I.G. moved to issue subpoenas for two rebuttal witnesses, both employees of BestCare. In their March 21, 2018 response, Petitioners agreed to produce one of the witnesses sought by the I.G. without need for a subpoena, but objected to the I.G.'s subpoena request for the other witness. Petitioners also filed a motion for leave to file seven additional exhibits (P. Exs. 44-50), which the I.G. did not oppose. I denied the I.G.'s motion for subpoenas on March 22, 2018.

From March 26 through 28, 2018, I held an in-person hearing where Petitioners cross-examined two of the I.G.'s witnesses, Leigh Del Rio (formerly Leigh Killough) and Mariel Filtz, while the I.G. cross-examined six of Petitioners' witnesses, Thomas Gustafson, Shavon Gifford (formerly Shavon Kingcaid), Kari Ramirez (formerly Kari McIntire), Ronald Morris, Petitioner Karim Maghareh, and Lewis Clarke. During the hearing, the I.G. submitted two additional exhibits, I.G. Exs. 34 and 35,[6] and Petitioners submitted one additional exhibit, P. Ex. 51. Tr. at 389, 567, 930. I admitted the following exhibits into the record: I.G. Exs. 2, 4-7, 10-18, 20, 22, 25-28, 30-32, and 35; and P. Exs. 1-3, 5, 7, 9, 11-19, 21-22,[7] 27-29, 31-41, and 44-51. Tr. at 16-18, 389, 552, 930. As I.G. Ex. 23 and P. Ex. 30 were statements made under oath from a witness not produced at the hearing, I excluded both of those exhibits from consideration. Tr. at 17.

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[5] I admitted P. Ex. 38 based on Petitioners' representation that they would re-file the exhibit to include a full copy of the document excerpted in the originally-filed version of P. Ex. 38. On March 19, 2018, Petitioners re-filed P. Ex. 38, which is labeled as document 82a in the official case file maintained in the DAB E-File system. That is the version of the exhibit that is admitted into the record.

[6] The I.G. inadvertently marked this exhibit as I.G. Ex. 36 for submission during the hearing, but because there was no I.G. Ex. 35, later re-marked it as I.G. Ex. 35.

[7] During the hearing, Petitioners substituted a corrected version of P. Ex. 22, with no objection from the I.G. Tr. at 34-35. References to that exhibit are to the corrected version of the exhibit, which is labeled as document 86a in the official case file maintained in the DAB E-File system.

In addition, I excluded from the record P. Exs. 25 and 26 because they are public records but noted the parties were free to cite them as such. Tr. at 17. I also provisionally admitted the following exhibits, subject to the outcome of the opposing party's cross-examination of the witness who produced those statements: I.G. Exs. 1 and 3 and P. Ex. 42 (statements under oath by Petitioner Karim Maghareh); I.G. Ex. 19 (direct testimony of Mariel Filtz with supporting documents); I.G. Ex. 21 and P. Exs. 10 and 43 (statements under oath by Kari Ramirez/McIntyre); I.G. Ex. 24 (direct testimony of Leigh Del Rio/Killough); P. Exs. 4 and 6 (statements under oath by Shavon Gifford/Kingcaid); P. Ex. 8 (direct testimony of Thomas Gustafson); P. Exs. 20 and 23 (statements under oath made by Ron Morris); and P. Ex. 24 (direct testimony of Lewis Clarke). Tr. at 17-18.[8]

All of these witnesses were produced at the hearing and subject to cross-examination, and neither party raised further objection to the listed exhibits or raised any concerns regarding that testimony during cross-examination that would affect admissibility. Accordingly, I admitted these exhibits into the record.

I also provisionally admitted into the record I.G. Exs. 8, 9, and 34, subject to authentication. Tr. at 18, 567-68. At the hearing, during re-direct examination, Dr. Maghareh expressed familiarity with the content of I.G. Exs. 8 and 9 that is relevant to this proceeding—the billing codes for the travel allowance related to laboratory sample collection. Tr. at 1014-16. The relevant content found in I.G. Exs. 8 and 9 is also fully consistent with other evidence already admitted. *See, e.g.*, I.G. Exs. 11 at 5-6; 16 at 52-53; 17 at 48-49. Petitioners' witness Shavon Gifford indicated she recognized I.G. Ex. 34. Tr. at 568-69. Moreover, it bears a similar marking in the lower right corner of the page that is found on the lower right corner of the first page of P. Ex. 31, which appears to be an exhibit marker for its use in a different proceeding (presumably, the District Court Case). Based on these facts, I find that I.G. Exs. 8, 9, and 34 have been sufficiently authenticated and admit them into the record.

Following the hearing, the parties filed a joint motion to withdraw several previously-filed exhibits (P. Exs. 31, 41, and 51 and I.G. Ex. 21) and file redacted versions of those exhibits that omit protected patient information. I granted the parties' motion by order dated April 6, 2018. The redacted versions of those exhibits were docketed as documents 87a, 87b, 87c, and 87d, respectively, in the official case file maintained in the DAB E-File system. The parties then filed post-hearing briefs (I.G. Br. and P. Br.).

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[8] I also provisionally admitted I.G. Ex. 29, subject to cross-examination. Tr. at 18. However, on further review, it is plain that the contents of I.G. Ex. 29 are largely reproduced verbatim, in a slightly different format, in P. Ex. 49. For this reason, I admit I.G. Ex. 29 into the record.

II. Issues

Whether the I.G. has a basis to exclude Petitioners from participating in Medicare, Medicaid, and all other federal health care programs for 15 years under 42 U.S.C. § 1320a-7(b)(7) and whether a 15-year exclusion is unreasonable. *See* 42 C.F.R. § 1001.2007(a)(1).

III. Applicable Law

A. Exclusion Authority

Section 1128(f) of the Act (42 U.S.C. § 1320a-7(f)) provides Petitioners with rights to an administrative hearing and judicial review of the final action of the Secretary of Health and Human Services (Secretary). The right to a hearing before an ALJ is set forth in 42 C.F.R. §§ 1001.2007(a) and 1005.2, and the rights of both the sanctioned party and the I.G. to participate in a hearing are specified by 42 C.F.R. § 1005.3.

The Secretary may exclude from participation in federal health care programs "[a]ny individual or entity that the Secretary determines has committed an act which is described in [42 U.S.C. §] 1320a-7a . . . ." 42 U.S.C. § 1320a-7(b)(7).[9] 42 U.S.C. § 1320a-7a forbids "[a]ny person (including an organization, agency, or other entity . . .)" from committing the following acts:

> [K]nowingly present[ing] or caus[ing] to be presented to an officer, employee, or agent of the United States, or of any department or agency thereof, . . . a claim (as defined in subsection (i)(2)) that the Secretary determines—
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> (A) is for a medical or other item or service that the person knows or should know was not provided as claimed, [or]
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> (B) is for a medical or other item or service and the person knows or should know the claim is false or fraudulent . . . .

42 U.S.C. § 1320a-7a(a)(1)(A), (B). A "claim" is "an application for payments for items and services under a Federal health care program . . . ." 42 U.S.C. § 1320a-7a(i)(2). An "'item or service' includes . . . any particular . . . service claimed to have been provided to a patient and listed in an itemized claim for payment, and . . . in the case of a claim based on costs, any entry in the cost report, books of account or other documents supporting such claim." 42 U.S.C. § 1320a-7a(i)(3). An "'agency of the United States' includes any contractor acting as a fiscal intermediary, carrier, or fiscal agent or any other

[9] The Secretary has delegated this exclusion authority to the I.G. 42 C.F.R. § 1001.901(a).

claims processing agent for a Federal health care program . . . ." 42 U.S.C. § 1320a-7a(i)(4). "The term 'should know' means that a person, with respect to information— . . . acts in deliberate ignorance of the truth or falsity of the information; or . . . acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required." 42 U.S.C. § 1320a-7a(i)(7). "The Secretary may not initiate an action under [42 U.S.C. § 1320a-7a] with respect to any claim . . . later than six years after the date the claim was presented . . . ." 42 U.S.C. § 1320a-7a(c)(1). This six-year statute of limitations similarly applies when the I.G. seeks to exclude an individual or entity pursuant to section 1128(b)(7) of the Act. *See Wesley J Hammer & Four Star Health Care Systems, Inc.*, DAB No. 1693 (1999).[10]

The Secretary has established criteria for deciding what is a reasonable length of an exclusion proposed pursuant to § 1128(b)(7) (42 C.F.R. § 1320a-7(b)(7)). There are five applicable criteria, consisting of the following:

> (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 claims;
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> (2) The degree of culpability;
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> (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);
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> (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
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> (5) Other matters as justice may require.

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[10] After the I.G. notified Petitioners that he was proposing to exclude Petitioners pursuant to section 1128(b)(7) of the Act, changes were made to 42 C.F.R. § 1001.901, the regulation implementing the Secretary's exclusion authority under section 1128(b)(7). On May 9, 2014, the Office of Inspector General (OIG) proposed adding a new subsection (c) to 42 C.F.R. § 1001.901 that would read, "An exclusion under this section is neither time barred nor subject to any statute of limitations period, even when the exclusion is based on violations of another statute that may have a specified limitations period." 79 Fed. Reg. 26,810, 26,815-16, 26,823 (2014). OIG published the final rule on January 12, 2017, effective February 13, 2017, adding a new subsection (c) that instead read "Limitations. The OIG may not impose an exclusion under this section more than 10 years after the date when an act which is described in section 1128A of the Act occurred." 82 Fed. Reg. 4100, 4101-02, 4114 (2017). I apply the six-year limitation imposed by the regulations in effect at the time the I.G. notified Petitioners of the proposed exclusion, as well as the Board's decisions interpreting that version of the regulation.

42 C.F.R. § 1001.901(b)(1)-(5). The exclusion is effective 60 days after receipt of the notice of proposed exclusion except where the individual or entity makes a written request for ALJ hearing and the I.G. "has determined that the health or safety of individuals receiving services under Medicare or any of the State health care programs does not warrant immediate exclusion," in which case the "exclusion will only go into effect as of the date of the ALJ's decision, if the ALJ upholds the decision to exclude." 42 C.F.R. § 1001.2003(a), (b).

The standard of proof is a preponderance of the evidence. 42 C.F.R. § 1001.2007(c). Petitioners bear the burden of proof and the burden of persuasion on any affirmative defenses or mitigating factors; the I.G. bears the burden on all other issues. 42 C.F.R. § 1005.15(b).

B. Medicare Claims

Section 1831 of the Act (42 U.S.C. § 1395j) establishes the supplementary medical insurance benefits program for the aged and disabled known as Medicare Part B. Section 1833 of the Act (42 U.S.C. § 1395*l*) establishes general rules for the payment of benefits under Medicare Part B. Among other things, section 1833 provides for reimbursement for eligible clinical diagnostic laboratory tests and, importantly, for a fee to cover certain costs associated with the collection of samples on which such tests are performed. 42 U.S.C. § 1395*l*(h). In relevant part, the Act requires the Secretary to do the following:

> [P]rovide for and establish . . . a fee to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect the sample . . . . In establishing a fee to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect a sample, the Secretary shall provide a method for computing the fee based on the number of miles traveled and the personnel costs associated with the collection of each individual sample . . . .

42 U.S.C. § 1395*l*(h)(3)(B).

The Medicare Claims Processing Manual (MCPM), Pub. 100-04, Chapter 16 § 60.2, contains the fee schedule and instructions to seek reimbursement from Medicare for travel costs of collecting samples. The fee schedule utilizes codes from the Healthcare Common Procedure Coding System (HCPCS) code set that a laboratory must use when seeking reimbursement for those travel costs. When filing claims for health care services and supplies under Medicare, providers and suppliers are required to use the applicable medical data code set, such as the HCPCS, that was valid at the time the health care was provided. 45 C.F.R. §§ 162.1000-.1011. There are two HCPCS codes associated with

billing for travel costs, P9603 and P9604. The first code, P9603, is associated with a "per mile travel allowance" used when "the average trip to patients' homes is longer than 20 miles round trip," while the second code, P9604, is associated with a "flat rate travel allowance" that is used when "average trips are less than 20 miles round trip." MCPM Ch. 16, § 60.2; I.G. Ex. 11 at 5-6.

At issue in this case is the propriety of Petitioners' use of code P9603 to bill Medicare for miles traveled solely by samples collected and shipped by BestCare without being accompanied by trained personnel.

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

My conclusions of law are set forth in bold and followed by pertinent findings of fact and analysis.

A. Petitioners' request for hearing was timely, and I have jurisdiction.

Petitioners timely requested a hearing. I therefore have jurisdiction to hear and decide this case. *See* 42 C.F.R. §§ 1001.2007(a)(1)-(2), 1005.2(a); *see also* 42 U.S.C. § 1320a-7(f)(1).

B. I am not precluded from considering this matter on its merits.

At the outset, I note that on April 18, 2018, subsequent to the hearing I held in this matter, the U.S. District Court with jurisdiction over the parallel civil action to this matter issued summary judgment against Petitioners, finding them liable under the False Claims Act (the same elements I am charged to consider as a basis for exclusion). On July 27, 2018, the District Court entered final judgment against Petitioners, who have appealed that judgment to the U.S. Court of Appeals for the Fifth Circuit. I.G. Notice of Final Judgment in U.S. District Court Proceeding.

The I.G. argues the District Court's grant of summary judgment amounts to issue preclusion as to whether Petitioners' claims were false within the meaning of the Act. I.G. Br. at 5. Petitioners argue more broadly that the District Court's issuance of summary judgment does not amount to judicial estoppel because that judgment is not final, as a motion for reconsideration is pending and because the government itself argued the judgment was not final. P. Br. at 26.

The I.G. has not argued that I should broadly apply estoppel in this case, so I need not address the validity of so doing. The I.G. does contend I should apply that doctrine more narrowly and rely on the District Court's finding that Petitioners' claims were false. Because the District Court's judgment covers a different time frame and is encompassed in a six-page order that does not make findings of fact beyond those necessary to issue

judgment, I do not believe it appropriate to bind myself to the District Court's summary assessment, accurate though it may be. By contrast, I denied the parties' motions for summary judgment, and held a full multi-day evidentiary hearing to receive facts into the record. I am also charged with determining whether there is a basis to exclude Petitioners *de novo*. It is therefore more appropriate to issue a decision on the merits in this case.

C. There is a basis for Petitioners' exclusion pursuant to section 1128(b)(7) of the Act.

Section 1128(b)(7) of the Act authorizes the Secretary to exclude from participation in Medicare, Medicaid, and all federal health care programs any individual or entity that has knowingly presented or caused to be presented to an agency of the United States claims for items or services where the individual or entity knew or should have known that the claims were false or fraudulent or that the items or services were not provided as claimed. 42 U.S.C. §§ 1320a-7(b)(7), 1320a-7a(a)(1)(A), (B). The I.G. has established these elements by a preponderance of the evidence.

1. Petitioners presented or caused to be presented to an agency of the United States the claims for services at issue in this case.

The Act provides that a contractor acting as a claims processing agent for a federal health care program is an "agency of the United States." 42 U.S.C. § 1320a-7a(i)(4). TrailBlazer, the administrative contractor charged with processing claims for reimbursement from the Medicare program on behalf of the Centers for Medicare & Medicaid Services (CMS) during the time period at issue in this case, was therefore an agency of the United States.[11]

The I.G. identified 571 claims Petitioners presented or caused to be presented to Trailblazer between August 21, 2009, and January 26, 2010 (the Relevant Period). I.G. Pre-hearing Br. at 17-18; I.G. Br. at 2; I.G. Ex. 18.[12] There is no dispute that the claims at issue constitute claims for services under the Act, as they are applications for payment for services (performance of eligible clinical diagnostic laboratory tests on samples, as well as collection of those samples) under Medicare. *See* 42 U.S.C. § 1320a-7a(i)(2), (3).

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[11] Trailblazer is no longer a Medicare administrative contractor. Centers for Medicare & Medicare Services, *Archives: A/B MAC Jurisdictions 4 and 7 (now known as Jurisdiction H)*, at https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/Archive-J4-and-J7.html (last modified Feb. 5, 2016).

[12] For reasons that are unclear to me, the I.G. did not submit the actual claim forms (Form CMS-1500) that Petitioners allegedly submitted to Trailblazer. However, Petitioners have not disputed presentment of the claims identified by the I.G. to Trailblazer for payment. While Dr. Maghareh denies personal involvement in presentment of these claims, he does not dispute that his signature appears on the 571 claims BestCare presented to Trailblazer that are at issue here. Thus, the lack of documentation of those claims does not affect my analysis or the outcome in this matter.

BestCare does not dispute its role in presenting these 571 claims to Trailblazer. I therefore conclude that BestCare presented the claims for services at issue in this case to an agency of the United States.

Dr. Maghareh contends he did not present or cause to be presented to Trailblazer the claims at issue in this case. He argues that BestCare's billing staff presented those claims, as did, for a limited time, "an independent billing consultant," to which he delegated billing responsibility. P. Pre-hearing Br. at 39. But Dr. Maghareh does not deny that his signature appeared on the claims submitted by BestCare or by Medigain. He instead asserts that "BestCare's staff electronically signed [his] name to the claim forms for reimbursement." *Id.* at 40. He denied "personally review[ing], sign[ing], or submit[ting] any claim for reimbursement." *Id.* at 40. During the hearing, Dr. Maghareh further testified under oath that he "didn't know [his] name was on these claims" because "[w]hen they installed the [billing] software in 2003, somebody typed [his] name on there" and he did not become "aware of it until this case came up." Tr. at 774. Based on his supposed delegation of billing responsibility and lack of personal involvement otherwise, Dr. Maghareh now disclaims any responsibility for presenting or causing to be presented to Trailblazer the claims at issue in this case.

I find Dr. Maghareh's claims that he was entirely unaware of his own company's billing practices entirely unpersuasive and incredible. Dr. Maghareh testified before me that he had "an understanding that [his] signature was going to be on the HCFA"[13] 1500 forms, an understanding he formed "[a]t some point before" January 2010. Tr. at 786-87. And in May 2011, again while under oath, Dr. Maghareh recognized HCFA 1500 forms presented to him by government counsel as claims submitted by BestCare, and conceded he had signed them electronically, because as president or owner of BestCare, his signature was required to present the claims. I.G. Ex. 3 at 181-83.

Beyond his testimony, the record clearly reflects his intimate involvement in BestCare's billing policy. Dr. Maghareh testified that he "instructed [BestCare's then-billing supervisor] Martha [Shirali] in 2007, 'Let's prorate the P9603 . . . ." I.G. Ex. 3 at 93, 136. He convened a July 2008 meeting with BestCare's then-chief financial officer, Barbara Franco, and then-billing supervisor, Kari Ramirez (McIntire), for the sole purpose of discussing billing for the travel allowance. I.G. Ex. 3 at 73, 103, 115-25, 129-31. At the end of the discussion, Dr. Maghareh "instructed – [he] told them, 'This is what I think. We need to do it this way. . . . I think this is the way we have to do.'" I.G. Ex. 3 at 118-19. His decision about proration became BestCare's billing practice, as he testified that following his decision, BestCare "[n]ever" changed their method of billing on this point. I.G. Ex. 3 at 127, 130. Indeed, Dr. Maghareh further explained that during the July 2008 meeting, he "instructed Ms. Franco and Ms. [Ramirez] that BestCare

[13] Health Care Financing Agency, the previous name for what is now CMS. *See* 66 Fed. Reg. 35,437 (July 5, 2001).

should follow that updated guidance [from CMS] to prorate mileage among the number of patients from whom samples were collected on a particular trip, beginning immediately." P. Ex. 42 at 11.[14] There is little doubt Dr. Maghareh had substantial control of billing decisions made by BestCare.

Dr. Maghareh's claim of ignorance as to the billing practices of his own company is even more difficult to credit given his longstanding and intimate involvement with BestCare. At all relevant times, he was BestCare's majority owner. I.G. Ex. 3 at 31-32; I.G. Ex. 4 at 6. On Medicare enrollment applications, Dr. Maghareh identified himself variously as BestCare's president, CEO, director, managing/directing employee, authorized representative, and authorized official. I.G. Ex. 4 at 7; I.G. Ex. 5 at 3-4, 7; I.G. Ex. 6 at 7. He started BestCare in 2002, and in 2008, by his own estimate, BestCare generated over $8 million in revenue. I.G. Ex. 3 at 83, 85. By 2010, BestCare's annual revenues approached $12 million. *Id.* at 84. By 2016, BestCare had three offices in Texas with 149 employees performing approximately five million tests annually for thousands of clients. P. Ex. 4 at 1. Given his close involvement in the company's billing practices and the expanding amount of revenue over the years, which inured chiefly to his benefit, it is simply inconceivable that Dr. Maghareh would now testify that he remained ignorant of how his company generated revenue.

Dr. Maghareh's attempt to shift blame for BestCare's billing practices to his employees is without merit. It is irrelevant that Dr. Maghareh did not personally sign the claim forms, which he claims his billing staff submitted with his signature affixed. Given the close control he demonstrated over his company I described above, it is clear he personally authorized the use of his signature to submit the claim forms at issue.

Even if he did simply rely on his staff to bill claims properly, as he claimed at the hearing (Tr. at 775, 786, 804, 805, 843-44), he did so at his own peril, for Dr. Maghareh would still bear the ultimate responsibility for claims billed under his name. As the Departmental Appeals Board (Board) has observed in another context, providers or suppliers who bill Medicare cannot rely on the mistakes of their billing agents as a defense, but instead are "ultimately responsible for the accuracy of . . . claims for Medicare reimbursement." *Louis J. Gaefke, D.P.M.*, DAB No. 2554 at 6 (2013); *see also* 73 Fed. Reg. 36,448, 36,455 (June 27, 2008) ("[W]e believe that providers and suppliers are responsible for the claims they submit or the claims submitted on their behalf [and] that it is essential that providers and suppliers take the necessary steps to ensure they are billing appropriately for services furnished to Medicare beneficiaries.").

[14] Ms. Del Rio confirmed this account before me, testifying that Dr. Maghareh directly instructed her how to bill for mileage, which further supports the conclusion that he personally was responsible for BestCare's billing practices related to code P9603. Tr. at 335; I.G. Ex. 24 at 3; I.G. Ex. 28 at 29-30. I find her credible, despite the extensive and often irrelevant cross-examination to which she was subjected. Ms. Del Rio had no incentive to misrepresent her interactions with Dr. Maghareh, and her testimony is consistent with the record overall.

In signing these forms, Dr. Maghareh agreed to legally and financially bind BestCare "to the laws, regulations, and program instructions of the Medicare program" and further agreed that he himself would "abide by the Medicare laws, regulations and program instructions that apply to" BestCare. I.G. Ex. 6 at 7; *see also* I.G. Ex. 4 at 7; I.G. Ex. 5 at 12. With his signature, Dr. Maghareh certified "that the services shown on this form . . . were personally furnished by me or were furnished incident to my professional service by my employee under my immediate personal supervision, except as otherwise expressly permitted by Medicare . . . regulations." I.G. Ex. 7 at 2. Dr. Maghareh's signature further reflected his understanding that "payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with [Medicare] laws, regulations, and program instructions . . . ." I.G. Ex. 6 at 7; *see also* I.G. Ex. 4 at 7; I.G. Ex. 5 at 12. By signing these forms and the claim forms, Dr. Maghareh accepted responsibility for the claims BestCare submitted to Medicare for payment, even where submitted by an employee or contractor.

Accordingly, I find Dr. Maghareh, along with BestCare, presented or caused to be presented the 571 claim forms at issue to Trailblazer, and thus to CMS/HCFA.

2. The claims Petitioners presented or caused to be presented to Medicare were false.

Petitioners billed the 571 claims at issue to Medicare under HCPCS code P9603, for reimbursement of travel costs associated with the collection of samples on which BestCare performed laboratory tests. I.G. Ex. 18. The Act unequivocally states that the purpose of the travel fee for sample collection at issue in this case is "to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect the [laboratory] sample [from] an individual who is homebound or an inpatient in an inpatient facility (other than a hospital)." 42 U.S.C. § 1395*l*(h)(3)(B) (emphasis added). Congress instructed that, "[i]n establishing a fee to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect a sample, the Secretary shall provide a method for computing the fee based on the number of miles traveled and the personnel costs associated with the collection of each individual sample." *Id.* (emphasis added).

Congress explicitly limited reimbursement for the travel expenses of "trained personnel" to collect samples, not to reimburse costs for simply shipping samples. There is simply no other way to read this exceedingly plain statutory language. Thus, there is no need to examine any supplemental guidance issued by the Secretary; the Act on its face prohibits laboratories from claiming the travel allowance fee for miles not traveled by a laboratory technician or phlebotomist. Any claims for travel mileage of a sample unaccompanied by trained personnel are not permitted under the Act and are therefore false.

Here, there is no dispute that until January 2010, Petitioners routinely submitted claims for travel of specimens unaccompanied by trained personnel. I.G. Ex. 3 at 169, 170. The I.G. proffered evidence demonstrating the 571 claims at issue were all submitted by BestCare during the Relevant Period, and that each claim included a request for reimbursement for at least 400 miles of travel. I.G. Ex. 18; I.G. Ex. 19. I.G. employee Mariel Filtz explained how she identified these 571 claims, sampled several dates during the Relevant Period, and found that every sample claim she inspected showed mileage for specimens traveling by air cargo, or by ground driven by a courier. I.G. Ex. 19; I.G. Ex. 32.

Ms. Filtz did not examine every single claim, but Petitioners have made no arguments contesting the I.G.'s assertions that all 571 claims involved billing for hundreds of miles of travel for samples that were at least in part unaccompanied by trained personnel.[15] They instead argue that under the guidance provided by the Secretary pursuant to the Act, they could not have known their claims were false, an argument I will address below. In the meantime, I conclude the 571 claims at issue reflect requests for per-mileage reimbursement for miles traveled by specimens, whether by ground or air, unaccompanied by trained personnel. Accordingly, under the clear language of the Act, these claims were false.

3. Petitioners should have known that the claims for services they presented or caused to be presented to Medicare were false.

Billing Medicare for mileage traveled by unaccompanied samples constitute false claims. Petitioners submitted such false claims to Medicare. But for Petitioners to be subject to exclusion under section 1128(b)(7) of the Act, they should have known that these claims were false.[16] 42 U.S.C. §§ 1320a-7(b)(7), 1320a-7a(a)(1)(B). This means Petitioners must have submitted their claims either "in deliberate ignorance of the truth or falsity" of those claims or "in reckless disregard of the truth or falsity" of those claims. 42 U.S.C. § 1320a-7a(i)(7).

Petitioners' argument that they could not have known the claims were false relies on the following points: (1) that the guidance provided by the Secretary was ambiguous enough such that a reasonable party in good faith could misconstrue it; and (2) that Petitioners relied on guidance provided by Trailblazer, instructions from Medigain, a third-party billing consultant they briefly employed, and audits performed by two Medicare contractors, all of which they claim tacitly or expressly endorsed their billing practice at

[15] Dr. Maghareh otherwise conceded this when he described BestCare's regular practice, which was to have phlebotomists collect a sample from a patient, process it a local facility, and then drop it off at an airport for shipment by Southwest Airlines to BestCare's primary facility in Webster, Texas. I.G. Ex. 3 at 170-172.

[16] I note that because I find Petitioners should have known their claims were false, I need not address whether they actually knew they were false.

issue here, leading Petitioners to believe they could in fact bill Medicare for travel by specimens, as opposed to travel by trained personnel. I address each of these in turn.

a. The Secretary's guidance, taken in whole, was not ambiguous.

Petitioners first and chiefly argue that the Secretary's guidance as to how to bill for travel was ambiguous enough to allow for their good-faith belief they could be reimbursed for shipment of samples unaccompanied by trained personnel. As discussed earlier, the Act itself explicitly limits reimbursement for travel to trained personnel, not samples. However, the Act delegated computation of that amount to the Secretary, who through CMS, elected to establish the method of computing the travel allowance through sub-regulatory guidance found in the MCPM, Pub. 100-04, Ch. 16 § 60.2. Petitioners rely on this particular provision of the manual to establish the ambiguity upon which they rely.

Section 60.2 of Chapter 16 of the MCPM describes two separate HCPCS codes, P9603 and P9604, which apply depending on the number of miles claimed. While P9604 provides only a flat rate for mileage up to twenty miles, P9603 allows a per-mile travel allowance for trips longer than twenty miles round-trip. The MCPM provides the following guidance, which, aside from the dollar amount, has remained unchanged during the Relevant Period:

> In addition to a specimen collection fee allowed under §60.1, Medicare, under Part B, covers a specimen collection fee and 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 may not be paid to a physician unless the trip to the home, or to the nursing home was solely for the purpose of drawing a specimen. Otherwise travel costs are considered to be associated with the other purposes of the trip.
>
> - The minimum "per mile travel allowance" is $1.00. 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 ($1.00 a mile in CY 2018) 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.*

Example 1: In CY 2018, a laboratory technician travels 60 miles round trip from a lab in a city to a remote rural location, and back to the lab to draw a single Medicare patient's blood. The total reimbursement would be $60.00 (60 miles x $1.00 a mile), plus the specimen collection fee.

Example 2: In CY 2018, a laboratory technician travels 40 miles from the lab to a Medicare patient's home to draw blood, and then travels an additional 10 miles to a non-Medicare patient's home and then travels 30 miles to return to the lab. The total miles traveled would be 80 miles. The claim submitted would be for one half of the miles traveled or $40.00 (40 x $1.00), plus the specimen collection fee.

MCPM, Pub. 100-04, Ch. 16 § 60.2 (emphasis added).

The I.G. points to the italicized portion of the MCPM's guidance to argue that the MCPM clearly prohibits laboratories from billing for miles traveled only by a sample without a laboratory technician (the "trained personnel" contemplated by the Act). I.G. Pre-hearing Br. at 9, 18-19; I.G. Br. at 2-3. Petitioners argue the language requiring actual travel by a technician is contained only in the second bullet point which is separated by the disjunctive "or" between the two bullets, meaning the language italicized above did not apply to billing under the first bullet, which describes the minimum flat-rate billing

allowed under P9603 pursuant to a per-mile travel allowance over twenty miles. P. Br. at 13-15.

The language from the first bullet above demonstrates the peril of using passive voice. Billing for travel of samples without a technician is clearly prohibited under the second bullet, where a contractor has established a higher per-mileage rate. Read in a hyper-technical manner, the bullet-point structure, coupled with the use of the disjunctive "or" between the two bullets, suggests that prohibition contained in the second bullet may not apply to the first bullet point.

But there is also sufficient language in the remainder of the text to cause a reasonable biller to take pause. This small section of the MCPM pertains to travel allowances, and this code, P9603, specifically to "Per Mile Travel Allowance." Within that subsection, the language prefatory to the bullet points states, "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*." MCPM, Pub. 100-04, Ch. 16 § 60.2 (emphasis added). Both bullet points fall under this language, making it less sensible to read only the second bullet as requiring travel by a technician.

The examples following the bullet points also militate against a disjunctive reading of the bullet points, as both examples given fall under the standard flat rate payment described in the first bullet, and both describe travel by a laboratory technician, not a sample. This further suggests the prohibitory language in fact applies to the first bullet point.

For these reasons, I do not find this section of the MCPM to be particularly ambiguous. However, I afford Petitioners the benefit of the doubt and find the guidance in the MCPM regarding travel is 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.

But Petitioners cannot prevail on the MCPM's ambiguity, because *all* the other guidance issued by CMS and its contractor uniformly and unequivocally stated that laboratories could not bill for miles traveled by unaccompanied samples under the minimum per-mile travel allowance. I.G. Ex. 12 at 3; I.G. Ex. 13 at 3; I.G. Ex. 14 at 4. CMS issued change request 5996 (CR 5996), dated May 30, 2008 (well before the Relevant Period), that made changes to the MCPM, including changes to § 60.2. I.G. Ex. 14 at 1, 7-9. In a preamble to these changes, CMS articulated its policy related to the travel allowance billed under codes P9603 and P9604. Regarding the per-mile travel allowance billed under P9603, CMS stated clearly, "At 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." I.G. Ex. 14 at 3.

To alert clinical laboratories affected by CR 5996, CMS issued a Medicare Learning Network (MLN) Matters article, MM5996,[17] containing almost the exact same language regarding P9603 billing: "At no time will a laboratory be allowed to bill for more miles than are reasonable or for miles that are not actually traveled by the laboratory technician." I.G. Ex. 13 at 3.

CMS issued another MLN Matters article, number MM6524, to alert clinical laboratories affected by a subsequent change request (CR 6524).[18] That article also states, with respect to P9603 billing, "At 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." I.G. Ex. 12 at 3.

Trailblazer's guidance at the time provided the same level of unambiguous clarity as that issued by CMS. I.G. Ex. 16 at 53; I.G. Ex. 17 at 49; I.G. Ex. 22. With respect to billing for P9603, Trailblazer's June 2007 Laboratory and Pathology manual clearly states, "Laboratories will not be allowed to bill for more miles than are reasonable or for miles not actually traveled by the laboratory technician." I.G. Ex. 16 at 53. Trailblazer's September 2009 Laboratory and Pathology manual contains slightly modified language regarding P9603 billing, citing CR 6524, but with no change in substance: "At 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." I.G. Ex. 17 at 49. Trailblazer also posted notice of CR 5996 on its website, including the following note regarding travel allowance billing that is clearly drawn from CR 5996: "*At 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.*" I.G. Ex. 22 (italics in original).

The foregoing guidance from CMS and Trailblazer, all available during the Relevant Period, clearly instructed laboratories and individuals 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. Any P9603 claim presented to Medicare by a laboratory or individual was a request that Medicare reimburse the laboratory or individual for miles traveled by a laboratory technician to draw such a sample(s).

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[17] CMS issues MLN Matters articles to "explain national Medicare policy in an easy-to-understand format. They focus on coverage, billing, and payment rules for specific provider types." CMS maintains these in a searchable format on its website. CMS, MLN Matters Articles, *available at* https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html (last updated Feb. 21, 2018).

[18] This change request was announced in an August 7, 2009 transmittal from CMS, which is a publicly available document. Transmittal 1790, Change Request 6524, *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1790CP.pdf (last accessed Aug. 12, 2018). This transmittal also included a statement of CMS's policy related to the travel allowance with language indistinguishable from that contained in CR 5996, as follows: "At 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."

Petitioners claim they never received these various sources of guidance, implying CMS was obliged to issue them to Petitioners directly before they could be expected to rely upon or be bound by them. P. Br. at 15-16. But Petitioners cite to no authority for this proposition; instead, as the U.S. Supreme Court has observed, a participant in the Medicare program has "a duty to familiarize itself with the legal requirements for cost reimbursement." *Heckler v. Community Health Servs.*, 467 U.S. 51, 64 (1984). Petitioners cannot reasonably expect CMS or Trailblazer to individually issue every possible piece of guidance to every provider or supplier; instead, as billers to the Medicare program, they were obligated to seek out such guidance and comply with the law. *See id.*

In any case, the record reflects that Petitioners in fact possessed written guidance from Trailblazer. Dr. Maghareh admitted that sometime in July 2008, he was given an annotated copy of a print-out from Trailblazer's website that references CMS's change request 5996. Tr. at 887-89. The print-out included a link to an MLN Matters article discussing the change request but also specifically states, "*At 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.*" I.G. Ex. 22 at 1 (italics in original). Dr. Maghareh also admitted that he read the entire document and "thought it was self-explanatory." Tr. at 891-92. Despite their claims to the contrary, it appears Petitioners had actual possession of the guidance that would have clearly put them on notice that they could not submit claims for reimbursement of travel mileage for specimens that traveled unaccompanied by a technician.

Petitioners nevertheless claim this guidance was substantially confusing to them, because the Trailblazer manual changed over time, and because these sources contradicted each other. P. Br. at 16-18. This argument is entirely without merit. There is no meaningful confusion among the sources of guidance available to Petitioners during the Relevant Period. For example, Petitioners focus on language from page 7 of CR 5996 to argue that the change request connected the prohibition on billing sample-only miles to situations where the contractor established a higher per-mile rate. *Id.* at 18 (quoting I.G. Ex. 14 at 7). But Petitioners ignore the clear policy language on page 3 of that change request, which stated, "At no time will the laboratory be allowed to bill . . . for miles that are not actually traveled by the laboratory technician." I.G. Ex. 14 at 3.

Similarly, Petitioners mischaracterize an article from the Trailblazer website, claimng it stated billing could be submitted for mileage "'actually traveled by a laboratory technician' when Contractors have 'established local policy to pay on a ***flat-rate basis only***.'" P. Br. at 18 (emphasis in original) (quoting I.G. Ex. 22). This misquotation is profoundly misleading. In full, the article actually says the following:

> ***Note:*** *Because of confusion that some laboratories have had regarding the per mile fee basis and the need to claim the minimum distance necessary for a laboratory technician to travel for specimen collection, some Medicare contractors have established local policy to pay based on a flat-rate basis only. At 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.*

I.G. Ex. 22 (emphasis in original). Petitioners' attempt to quote this otherwise clear statement out of order and in fragments does not serve their claim they acted in good faith particularly well.

Contrary to Petitioners' assertions, the policy language contained in CR 5996 is entirely consistent with the article on Trailblazer's website (I.G. Ex. 22) and article MM5996 (I.G. Ex. 13 at 3), both of which described CR 5996. These sources all make it abundantly clear that laboratories are not allowed to bill code P9603 for miles not actually traveled by a laboratory technician.

Petitioners' attack on the clarity of Trailblazer's 2007 and 2009 manuals is equally unavailing. Petitioners' own expert did not think these manuals were vague and contradictory about whether a laboratory could bill the travel allowance for shipment of specimens. Tr. at 483. Petitioners even seem to acknowledge that the 2007 Trailblazer manual clearly prohibited billing miles traveled only by specimens, as they recognize that it states that "[l]aboratories will not be allowed to bill for . . . miles not actually traveled by the laboratory technician" in a stand-alone paragraph. P. Br. at 17 (quoting I.G. Ex. 16 at 53). Petitioners point out that the 2009 Trailblazer manual contains this prohibitory language in the same paragraph as another sentence discussing contractors' authority to establish a higher per-mile rate, similar to the MCPM. P. Br. at 17 (citing I.G. Ex. 17 at 49). Unlike the MCPM, however, there is nothing in the 2009 Trailblazer manual suggesting that the prohibitory language may be limited only to situations where the contractor established a higher per-mile rate. I.G. Ex. 17 at 49. Neither manual was ambiguous in prohibiting laboratories from billing for specimen-only travel, whether read alone or in context with other guidance from CMS and Trailblazer.

To the extent Petitioners rely on Dr. Gustafson's testimony to establish these sources of guidance were contradictory or confusing, I reject Dr. Gustafson's conclusion. Tr. at 520-21 (testifying to his "belie[f] that the totality of the guidance available and most relevant to the provider was not fully clear"). As the I.G. points out, Dr. Gustafson's conclusion was essentially a legal one, as it was based on his own review of the applicable legal authorities. I.G. Br. at 6 n.1. As such, I see no basis to substitute his conclusions or analysis for my own, and accord his opinion - that the available guidance was confusing - no weight in my decision. Tr. at 521.

Petitioners also contend it would have been unreasonable to disregard the MCPM in favor of Trailblazer's manuals or web postings. P. Br. at 16. But their reliance on the "pyramid of information" described by Dr. Gustafson is inconsistent and self-serving. Tr. at 459, 484. If they in fact believed the MCPM trumped the guidance found in Trailblazer's manuals, its websites, and Medicare's MLN articles, Petitioners could have simply looked higher up the pyramid, to the Act itself, which plainly forbade the billing at issue here. Instead, Petitioners chose to fixate on the only source of guidance which would arguably allow them to bill for miles traveled by samples without technicians.

Petitioners' claim to have been subject to substantial confusion because other sources of guidance contradicted the MCPM is a false dilemma because while the MCPM, read generously, might have been ambiguous, it was not contradictory to the supplemental guidance made available by CMS and its contractor. Indeed, Petitioners' own witness, Dr. Gustafson, stated that where a "provider believes [Medicare's] rules are not clear, then I believe there's an obligation to investigate, to look at website information for instance or to call up the Medicare contractor." Tr. at 422. Dr. Gustafson thought that the language contained in the supplemental guidance provided by Trailblazer would put any party reading it on notice that Petitioners' billing scheme was problematic, constituting a "red flag." Tr. at 455.

I conclude it was simply reckless for Petitioners to consult only one source of guidance, the MCPM, to the exclusion of all the other guidance discussed above.[19] As billers to the Medicare program, Petitioners were obligated to bill in a legally compliant fashion, which at a minimum meant consulting sources of guidance that were freely available to them. When read together, those sources of guidance make abundantly clear that the reimbursement by Medicare for miles traveled is limited to circumstances where a technician or other trained personnel accompanies laboratory samples. Taken together, these sources of guidance, including the MCPM, were a "red flag" Petitioners were obligated to consider. Their failure to make a reasonable inquiry of those sources, and instead fixate on the only source that might support their billing practice, constitutes "deliberate ignorance" or "reckless disregard" as to the truth or falsity of the claims they submitted. 42 U.S.C. § 1320a-7a(i)(7).

b. Petitioners did not reasonably rely on their communications with third parties.

The evidence of record shows there was enough public guidance available to Petitioners to make plain their efforts to bill for travel of unaccompanied samples were improper.

[19] Petitioners' insistence on relying solely upon the MCPM makes even less sense given that even Petitioners' expert acknowledged the MCPM was aimed chiefly at CMS contractors, not providers or suppliers. P. Ex. 8 at 4; Tr. at 424, 438.

Petitioners' defense to the clarity of that guidance is that various entities, including CMS' administrative contractors, ratified Petitioners' billing practices. P. Pre-hearing Br. at 31-33; P. Br. at 2-4, 6-8.

Aside from CMS' contractors, Petitioners also point to submissions of the same type of false claims on their behalf by Medigain, an outside billing company they hired to provide billing services for a brief period of time. P. Pre-hearing Br. at 31, 33; P. Br. at 8. They also purportedly relied on comprehensive audits of their travel billing conducted by TriCenturion and CERT DC, both Medicare contractors. P. Pre-hearing Br. at 33; P. Br. at 10-13.

Petitioners argue that the actions of these outside authorities undermine the I.G.'s position that they should have known they were submitting false claims to Medicare. P. Pre-hearing Br. at 31-33; P. Br. at 12-13. I do not find these arguments persuasive, because none of these outside parties were fully confronted with the exact issue of how Petitioners billed travel.

Regarding the latter two arguments, I simply note there is no evidence to suggest Petitioners explicitly made known to any of these entities that they were submitting claims for mileage traveled by samples unaccompanied by a technician, in contravention of the plain language of the statute and available guidance. Medigain was employed to help process billing during a backlog. I.G. Ex. 21 at 42. That company was not brought on to undertake a forensic audit of BestCare's billing practices. Moreover, Medigain was not solely responsible for submitting travel mileage claims during the brief period it assisted with billing. As Kari Ramirez testified, Medigain initially did data entry and only some billing and coding; BestCare's staff continued to bill and code as well. *Id.* Petitioners have not proffered evidence to show they had communicated the details of how their mileage was billed with sufficient detail to put Medigain on notice they were billing for travel of unaccompanied samples. Petitioners cannot identify any actual endorsement by Medigain of that practice.

Similarly, there is no evidence in the record that TriCenturion or CERT DC, Medicare contractors who paid Petitioners' false claims, were made aware of BestCare's practice of billing for shipping samples by air, unaccompanied by a technician. Neither contractor explicitly endorsed this practice; the fact that BestCare was able to successfully submit invalid claims is hardly justification for doing it in the first place.

Finally, Petitioners assert they relied on assurances from Trailblazer itself, claiming Dean Richardson, a third-tier representative from Trailblazer they contacted on two occasions, explicitly endorsed the billing practice at issue here. P. Pre-hearing Br. at 12-13; P. Br. at 6-8. The record, however, does not support Petitioners' claim that Trailblazer knowingly endorsed their billing for unaccompanied travel for samples.

Petitioners focus on two interactions with Mr. Richardson;[20] the first took place in July 2008, after a series of interactions between BestCare and Trailblazer representatives escalated the matter to Mr. Richardson, a third-tier representative.[21] I.G. Ex. 27 at 1-2. Kari Ramirez (identified as 'Carrie' in Trailblazer's call logs) spoke with Mr. Richardson, whose contemporaneous summary of that conversation clearly reflects his understanding that Ms. Ramirez called to clarify whether BestCare could bill for air miles traveled by a technician and a sample, *not* whether a sample could travel unaccompanied by a technician at all ("I spoke with Carrie . . . we do not have any guidelines that state the specimen could not be collected and mileage not be paid when traveling by 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.G. Ex. 27 at 2 (emphasis added).

It is clear that Mr. Richardson by no means understood that BestCare had sought his consent to the concept of unaccompanied sample travel. Instead, his note, as well as the prior notes memorializing earlier conversations with lower-tiered Trailblazer staff, all clearly indicate that Trailblazer understood BestCare to have inquired as to the propriety of billing for technicians traveling with samples by air instead of by ground. *Id.* at 1-2. Critically, Mr. Richardson also provided Ms. Ramirez a link to Trailblazer's website that linked to CR 5996 and the accompanying MLN Matters article. *Id.* at 2. Ms. Ramirez' contemporaneous notes of that conversation are recorded on an actual printout of CR 5996, which explicitly forbids billing for mileage not traveled by a technician. I.G. Ex. 22. Moreover, her notes reflect she also understood her conversation with Mr. Richardson to relate to air travel versus ground travel, remarking that "Dean from Part B . . . states no guidelines stating you can't charge the mileage to fly specimens. So yes that is okay to charge for flight mileage." *Id.*

Ms. Ramirez testified in 2011 that she "explained to [Dean Richardson] there's not going to be anybody with it because the phlebotomist drives it to the airport, drops it off, until it gets back to Houston. So I did explain that, that we weren't going to have anybody on the plane with it." I.G. Ex. 21 at 24. But at the hearing before me, when initially asked, "What issue were you raising with [Dean Richardson]?" Ms. Ramirez responded "Just if it was ok that we were charging the mileage from . . . flying the specimens from one lab

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[20] Dr. Maghareh also testified to an alleged call or voicemail message to a "Cindy Henry" at Trailblazer, where he allegedly provided a very specific description of BestCare's process for transporting samples. Tr. at 837-40. But there is no tangible evidence of such an interaction, and Petitioners fail to even address this alleged contact in either their pre- or post-hearing briefs. As such, I give no credence to Dr. Maghareh's vaguely recalled memory of a conversation where he happened to have explicitly provided the exact information needed to bolster Petitioners' detrimental reliance argument, particularly where Petitioners' counsel appear to have abandoned it as a quantum of evidence.

[21] Prior interactions concern proration of travel mileage where multiple samples are collected, not whether a sample could travel unaccompanied by a technician. While the issues of proration and ground vs. air mileage have been argued to various degrees by the parties, my decision finds a basis for exclusion solely in Petitioners' use of code P9603 to bill Medicare for mileage of samples that traveled unaccompanied by a technician.

to another to be processed." Tr. at 669-70. Ms. Ramirez eventually modified her answer under re-direct to state she had explicitly told Mr. Richardson the specimens traveling by air were unaccompanied by a technician. *Id.* at 713.

I do not find Ms. Ramirez' claim that she explicitly advised Mr. Richardson of BestCare's intent to ship specimens by air without a technician to be credible. Her claim is inconsistent with her own contemporaneous notes, as well as those of Mr. Richardson, which relate solely to the question of whether BestCare could bill for air mileage traveled by a technician instead of ground mileage. I.G. Ex. 22; I.G. Ex. 27 at 2. By contrast, Mr. Richardson's contemporaneous notes are consistent with his later testimony in 2013. I.G. Ex. 33. I therefore find Mr. Richardson's recollection of that conversation to be more credible.

Even if Ms. Ramirez misunderstood the advice Mr. Richardson gave her verbally, he also provided a link to both the CMS change request and the MLN Matters article on Trailblazer's website, both of which unequivocally forbade billing for mileage where a sample was unaccompanied by a technician. Petitioners either deliberately ignored or recklessly disregarded Mr. Richardson's advice and the written guidance he provided to Ms. Ramirez.

The second interaction took place between Mr. Richardson and Dr. Maghareh himself, a few months later. P. Pre-hearing Br. at 13; P. Br. at 11. Dr. Maghareh opted to record some but not all of this conversation with Mr. Richardson. I.G. Ex. 31. Petitioners characterize the exchange as instructions from Trailblazer permitting BestCare to use the P9603 code to bill for miles traveled by a specimen unaccompanied by a technician. P. Pre-hearing Br. at 13. But nothing Mr. Richardson said can be reasonably construed as such an instruction. Their conversation begins, at least as recorded, with Dr. Maghareh inquiring how to get Trailblazer to afford him a higher per-mile flat rate. I.G. Ex. 31 at 1-6. Dr. Maghareh transitions to discussing reimbursement for air versus ground mileage, referencing the conversation Mr. Richardson had with Ms. Ramirez. *Id.* at 6. He asks Mr. Richardson to reiterate the advice he had previously given to Ms. Ramirez; Mr. Richardson does so, while Dr. Maghareh interjects several references to specimens flying:

> 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--
>
> Maghareh: Mm hmm.
>
> Richardson: -- in other words, there-- she was wanting to fly.
>
> 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 have been.
>
> Maghareh: I see. So . . . it's okay to figure the ground mileage and then use it for the specimen flying?"
>
> Richardson: Right.
>
> Maghareh: I see . . . they just have to figure out ground mileage from BestCare Houston to the other place and then use that mileage?
>
> Richardson: That's right.
>
> Maghareh: Okay. And just fly the specimen itself?
>
> Richardson: Right.

Id. at 6-7.

For his part, upon hearing this recording, Mr. Richardson made it clear that he understood the situation posed by Dr. Maghareh to describe air travel by technicians bearing samples. I.G. Ex. 33 at 98-105. Mr. Richardson felt strongly enough about this issue that he annotated the record of his interaction with BestCare to clarify that Dr. Maghareh implied the specimens referenced in their conversations 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. I.G. Ex. 27 at 2.

Petitioners' entire claim for reliance is premised on Dr. Maghareh's references to "specimens flying" and "fly the specimen itself" while speaking with Mr. Richardson about how to use ground mileage to calculate travel by air. Given Mr. Richardson's reaction to Petitioners' characterization of his advice, I am not at all persuaded that Petitioners actually relied on this minimal dialogue with Mr. Richardson in good faith. But if they did, it was a flimsy reed indeed upon which to rest millions of dollars' worth of billing to the government. Petitioners did not reasonably rely on this brief dialogue between Dr. Maghareh and Mr. Richardson.

In sum, the Act and the various sources of guidance emanating therefrom clearly put Petitioners 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. The MCPM was not ambiguous when read with all the other available sources of

guidance, including Trailblazer's 2007 Laboratory and Pathology Manual (I.G. Ex. 16 at 53), CMS's change request 5996 (I.G. Ex. 14 at 3), CMS's MLN Matters article MM5996 (I.G. Ex. 13 at 3), and Trailblazer's website referencing the change request and linking to the MLN Matters article (I.G. Ex. 22).

Petitioners were obligated to seek out and be aware of these sources of guidance in order to participate as billers to the Medicare program in a legally compliant fashion. *Community Health Servs.*, 467 U.S. at 64. The record shows Petitioners had actual notice of guidance that would have resolved any alleged confusion regarding their billing practice, namely a print-out from Trailblazer's website containing language that prohibited their billing practices, as well as links to CMS's change request and the MLN Matters article that each contained similar prohibitory language. Petitioners had no legitimate need to contact Mr. Richardson for additional guidance. Their attempt to hang a significant and highly lucrative billing practice around his neck is futile. Petitioners acted recklessly when they disregarded CMS's and Trailblazer's clear guidance prohibiting their billing practice, and instead sought to have Mr. Richardson provide sufficient cover to permit their billing practice without ever explicitly and thoroughly describing it to him.

For the foregoing reasons, I conclude Petitioners should have known their claims were false. I find there is a basis to exclude Petitioners from participation in Medicare, Medicaid, and all other federal health care programs under 42 U.S.C. § 1320a-7(b)(7)

4. Petitioners' equitable defenses do not serve to undermine the I.G.'s basis for excluding them.

Petitioners assert various equitable defenses to the I.G.'s exclusion action, including reliance, waiver, laches, estoppel, and failure to mitigate damages. P. Pre-hearing Br. at 43-45. I have already concluded above that Petitioners knowingly presented or caused to be presented to an agency of the United States multiple claims for services that Petitioners should have known were not provided as claimed or were false or fraudulent. Therefore, the I.G. had a basis to exclude Petitioners from participation in Medicare, Medicaid, and all federal health care programs. Consequently, I have no authority to grant equitable relief from the I.G.'s exercise of discretion to exclude Petitioners under section 1128(b)(7), regardless of the theory offered in support of equitable relief.

Even if I had equitable authority, I would not grant such relief here. Petitioners' supposed reliance on various audits, a history of payments by government contractors, and the alleged independent billing expertise of a consultant was objectively unreasonable given the overwhelmingly clear guidance that specifically forbade Petitioners from billing for miles traveled by a laboratory sample unaccompanied by a laboratory technician.

Regarding estoppel and waiver, Petitioners have presented no evidence of affirmative misconduct to support such defenses. *See US Ultrasound*, DAB No. 2302 at 8 (2010) ("[E]stoppel against the federal government, if available at all, is presumably unavailable absent affirmative misconduct, such as fraud, by the federal government" (internal quotation marks omitted).).

Regarding laches, such a claim would more properly be brought in a civil action against the government (such as the District Court Case) as a defense to the government's claim for repayment. Moreover, specifically as it relates to this case, any delay by the I.G. in deciding to exclude Petitioners under section 1128(b)(7) of the Act prejudiced the I.G. at least as much as it prejudiced Petitioners, given the six-year retrospective window upon which the I.G. was required to base an exclusion action. Furthermore, any prejudice to Petitioners was minimal given the parallel District Court Case, which had been ongoing for years prior to the I.G.'s exclusion action. Given the substantial overlap between that case and this one, Petitioners have had ample opportunity to develop the record and defend their conduct.

Finally, the defense of failure to mitigate is irrelevant in contesting the basis for the I.G.'s exclusion. The I.G.'s exclusion authority is not predicated on the government suffering any damages. As I already explained at length above, the I.G. may exclude Petitioners based solely on their act of presenting or causing to be presented to Medicare claims for services that they knew or should have known were false or fraudulent or were for services that were not provided as claimed. Even if the government mitigated its damages by refusing to reimburse Petitioners for any of the claims at issue in this case, the I.G. would still have a basis to exclude Petitioners.

5. The statute of limitations is not implicated by discussion of Petitioners' conduct preceding the six-year timeframe that forms the basis of the proposed exclusion.

Petitioners contend the I.G. improperly relied on claims that they submitted to Trailblazer more than six years prior to the I.G.'s notice of proposed exclusion. P. Pre-hearing Br. at 45-46. As already noted above, "[t]he Secretary may not initiate an action under [42 U.S.C. § 1320a-7a] with respect to any claim . . . later than six years after the date the claim was presented . . . ." 42 U.S.C. § 1320a-7a(c)(1). This six-year statute of limitations similarly applies when the I.G. seeks to exclude an individual or entity pursuant to section 1128(b)(7) of the Act. *See Wesley J Hammer*, DAB No. 1693.

Petitioners' argument is plainly without merit. The I.G. proposed Petitioners' exclusions based solely on claims they presented to Trailblazer during the Relevant Period, which began August 21, 2009, six years before the date of the I.G.'s notice of proposed exclusion. P. Ex. A to RFH at 1-3; I.G. Pre-hearing Br. at 17-18. Any discussion of prior conduct, including that adjudicated in the District Court Case, is essentially relevant

background in this matter. In any event, my review of the I.G.'s basis for excluding Petitioners is *de novo*, and I have found the I.G. had a basis to exclude Petitioners based solely on the claims they submitted within the six-year statute of limitations (i.e., on or after August 21, 2009).

To the extent that Petitioners are arguing that the I.G. (and I) must completely ignore all of Petitioners' misconduct prior to the six-year limitations period, they are mistaken. Unlike other bases for exclusion, Congress gave the Secretary discretion to determine the appropriate length of an exclusion imposed pursuant to section 1128(b)(7). To make that determination, the Secretary explicitly instructed the I.G. to consider whether an individual or entity excluded pursuant to section 1128(b)(7) "has a documented history of . . . civil or administrative wrongdoing" and "[o]ther matters as justice may require" when determining the length of the exclusion. Therefore, while the I.G. may not look to conduct outside the six-year period to form the basis of the exclusion, it is not merely appropriate but necessary for me to consider Petitioners' prior actions when determining whether the period of exclusion proposed by the I.G. is reasonable.

D. An exclusion of 15 years is reasonable because the circumstances surrounding Petitioners' billing scheme indicate Petitioners are highly untrustworthy, and the mitigating evidence in Petitioners' favor at best serves to protect Petitioners from what might otherwise be a much lengthier exclusion.

I must uphold the IG's determination as to the length of exclusion unless it is unreasonable. 42 C.F.R. § 1001.2007(a)(1)(ii). I may not "substitute [my] judgment for that of the I.G. or . . . determine what period might be 'better.'" *Robert Kolbusz, M.D.*, DAB No. 2759 at 5 (2017) (citing, *inter alia*, *Craig Richard Wilder*, DAB No. 2416 at 8 (2011)); *see Michael D. Dinkel*, DAB No. 2445 at 19 (2012). Rather, I consider only "whether the period of exclusion imposed by the I.G. was within a reasonable range . . . ." *Wilder*, DAB No. 2416 at 8; *see also* 57 Fed. Reg. 3298, 3321 (Jan. 29, 1992). The criteria for assessing whether the length of exclusion is within a reasonable range are as follows:

> (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

(5) Other matters as justice may require.

42 C.F.R. § 1001.901(b)(1)-(5).

1. The nature and circumstances of the conduct forming the basis of the exclusion warrant a 15-year period of exclusion.

The nature and circumstances of Petitioners' conduct support the I.G. proposed term of exclusion. This factor requires consideration of the length of time the conduct took place, the number of acts, any evidence of a pattern, and the amount claimed. 42 C.F.R. § 1001.901(b)(1). The I.G.'s proffered basis for exclusion is limited to Petitioners' conduct within a six-year period from August 2009 to August 2015. But these acts did not occur in isolation within this timeframe. Petitioners' fraudulent conduct resulted in a civil action that makes it clear their improper billing practices with respect to Code P9603 began as early as 2004. I.G. Notice of District Court Opinion and Order on Summary Judgment, Attachment A. During this period of time Petitioners submitted over 26,000 claims which were paid, resulting in over $10,000,000 in losses to the government, a staggering amount. *Id.*

I note that even if I constrained myself to look at only the conduct during the Relevant Period, this factor would still militate against Petitioners, who submitted 571 claims to Medicare, all of which were improper, and each of which amounted to over 400 miles in invalid mileage. Assuming Petitioners received $1.00 per mile claimed, these claims represent over $228,000 in improper billing, a significant loss to the government within such a relatively short period of time.

Petitioners also claim that there is no pattern of behavior, but that is plainly wrong. The pattern is somewhat obvious – despite many sources of guidance suggesting it was improper, Petitioners repeatedly used a billing code 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. This pattern preceded the Relevant Period for years and did not stop until the government began to scrutinize Petitioners' conduct.

Petitioners also somewhat bizarrely claim these 571 claims represent only a miniscule percentage out of all the claims they submitted, an exercise of "bad math." P. Br. at 10,

23. The "bad math" here stems from Petitioners' unfounded assumption that all the remaining claims were correct. But the I.G. did not include, as a basis for exclusion, every claim where Petitioners submitted invalid claims for samples traveling without a technician. The I.G. instead selected claims that were most egregious in terms of loss to the government - those exceeding 400 miles of travel. There are many more potential bad claims that resulted from Petitioners' profiteering. Minimizing their course of conduct to constitute "bad math" minimizes their responsibility and demonstrates Petitioners' ongoing indifference to the nature of their misconduct.

2. The degree of culpability is high.

I find Petitioners were highly culpable. Their actions were not merely negligent or the product of "bad math." Petitioners either acted by design or with reckless disregard for the law as it pertained to an obvious limitation against their billing practices. They were not victims of careless billing by others to whom they had delegated such responsibility.

The record reflects that Dr. Maghareh was closely involved in the operation of his company from its inception and exercised significant control over his billing staff. By his own admission, he knew he received a "significant" amount of revenue through travel reimbursement. Tr. at 808. Petitioners' witness Kari Ramirez maintained that Dr. Maghareh expected her to keep him informed on any developments that would affect the bottom line in terms of BestCare's revenues. Tr. at 625. Leigh Del Rio similarly confirmed he wanted updates as to the status of claims, including how many were being paid and for how much. I.G. Ex. 28 at 73.

There is nothing in the record to suggest Petitioners were simply absentee landlords who had no agency concerning their billing practices. Certainly, no one benefited to a greater degree than Petitioners from their billing scheme – in 2009 alone, the last year of billing before the government interceded, BestCare generated over *half* of its total Medicare revenue, over $3.5 million, simply for billing miles traveled by samples without a technician. I.G. Br. in Support of Summary Judgment, Attachment B at 5. Dr. Maghareh personally netted millions of dollars in the form of distributions he paid himself. I.G. Notice of U.S. District Court Action, Attachment A at 2. I conclude a high degree of culpability must rest with Petitioners, not their staff.

3. The parallel District Court Case and judgment demonstrate a history of civil wrongdoing.

On July 27, 2018, the District Court entered final judgment against Petitioners in the parallel civil action to this matter, finding them liable under the False Claims Act (the same elements I am charged to consider as a basis for exclusion). I.G. Notice of Final Judgment in U.S. District Court Proceeding. The I.G. contends this civil judgment, based on the same facts and circumstances that form the basis for an exclusion, constitutes an

adverse action. I.G. Pre-hearing Br. at 49 (citing *Stephen Winters*, DAB CR1246 at 27 (2004)); I.G. Br. at 28-29 (same). The plain language of the regulation refers to an "adverse action by any Federal, State or local government agency or board." 42 C.F.R. § 1001.901(b)(4). It is not clear to me that a federal district court can properly be considered an "agency or board." Therefore, I did not consider this factor in determining the reasonableness of the 15-year exclusion period.

However, the regulatory factor at 42 C.F.R. § 1001.901(b)(3) refers to "a documented history of criminal, civil or administrative wrongdoing." The civil judgment recently entered by the District Court against Petitioners for an amount exceeding $30 million clearly illustrates civil wrongdoing. I.G. Notice of Final Judgment in U.S. District Court Proceeding, Attachment B.

The I.G. obviously could not have considered this judgment at the time the proposed exclusion was issued in August 2015, but the U.S. Department of Justice initiated this civil action in 2011, and the District Court issued partial summary judgment against Petitioners with an order for equitable relief exceeding $10 million in 2014. I.G. Br. in Support of Summary Judgment, Attachment B. Accordingly, there is evidence of prior documented wrongdoing the I.G. could have considered. And as my own review is *de novo*, it is appropriate to consider such prior history when assessing the reasonableness of the proposed exclusion period.

The phrase "documented history of criminal, civil or administrative wrongdoing" appears intended to capture bad acts beyond those formally subjected to judgment - otherwise, the Secretary could simply have referred to prior judgments. In this case, the imposition of partial summary judgment and the award of substantial equitable relief against Petitioners seems exactly the sort of documented history of wrongdoing this regulatory factor was intended to capture.

I therefore find Petitioners had a documented history of civil wrongdoing that would in part justify a 15-year exclusion period. However, I further observe that a finding to the contrary regarding this factor would not affect the outcome; the egregious nature and circumstances of Petitioners' conduct, coupled with their high degree of culpability, demonstrate such profound untrustworthiness that dispensing with this regulatory factor altogether, a 15-year period of exclusion is still entirely reasonable.

4. Other matters as justice may require do not warrant a lower exclusion period than 15 years.

The final regulatory factor I must consider in assessing the reasonableness of the I.G.'s proposed exclusion period is elastic, and the Board has characterized it as "open-ended." *Thomas M. Horras & Christine Richards*, DAB No. 2015 at 57 (2006). The Board has also observed that, aside from deterrence, the purpose of the exclusion authority is to

prevent untrustworthy providers from harming health care programs and their beneficiaries by their future misconduct. *John N. Crawford, Jr., M.D.*, DAB No. 1324 at 7-8 (1992) (citations omitted). Thus, it would appear that no matter how open-ended, my inquiry must at least consider how these other matters would tend to reflect upon Petitioners' trustworthiness. *Rudra Sabaratnam, M.D. & Robert I. Bourseau*, DAB CR1660 at 25 (2007).

Petitioners baldly claim the Medicare program needs no protection from them. P. Br. at 25. This is clearly not true. Petitioners have bilked the Medicare program, and thus the taxpayers, of millions of dollars in undeserved profits that may never be disgorged. Their billing scheme involved sending samples by air hundreds of miles for no discernible reason aside from maximizing billing revenue solely for their benefit. They clearly should not be trusted to access program funds.

Petitioners also assert they provide quality patient care and that their exclusion would negatively impact the current level of service in the areas in which they operate. *Id.* I do not credit the testimony of their witnesses, Director Morris and Dr. Clarke, to the extent they assert Petitioners' absence will put patients at risk, because Petitioners have failed to establish a paucity of laboratories in the Houston, Texas area that could provide similar services. Neither witness provided anything more than anecdotal praise for Petitioners and what amounts to unfounded speculation as to the effect of Petitioners' absence in their respective health care domains. Absent any actual evidence to support their claim, I am unconvinced that the Houston, Texas area will sustain any meaningful negative impact from Petitioners' absence. The Medicare program, on the other hand, will undoubtedly be better off without them.

Petitioners also argue this exclusion will be punitive with respect to BestCare's 175 employees. *Id.* I am keenly aware of the impact of my decision, but the blame for the imminent loss of employment for BestCare's employees rests solely with Petitioners, and no one else. Their reckless misconduct put the economic stability and wellbeing of their employees at grave risk. If anything, this argument reinforces the view that Petitioners are simply too untrustworthy to participate as billers to the Medicare program.

Having carefully considered all the relevant regulatory factors, I cannot say the I.G.'s selection of a 15-year exclusion period is unreasonable. In fact, given the massive losses sustained by the Medicare program due to Petitioners' malfeasance, as well as their ongoing efforts to shirk responsibility, the I.G. has, in my view, exercised considerable restraint in selecting a 15-year period of exclusion.

V. Conclusion

Petitioners are excluded from participation in Medicare, Medicaid, and all federal health care programs for 15 years pursuant to section 1128(b)(7) of the Act (42 U.S.C. § 1320a-7(b)(7)). The exclusion is effective from the date this decision is issued. 42 C.F.R. § 1001.2003(b).

Bill Thomas
Administrative Law Judge