Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Inspector General,
U.S. Department of Health & Human Services,
Petitioner,

v.

Mohammad Siddique, M.D.
and Shoals Medical Group, LLC,
Respondents.[1]

Docket No. C-15-4156

Decision No. CR4692

Date: August 29, 2016

DECISION

From April 3, 2011 through September 27, 2012, Respondents, Mohammad Siddique, M.D. and Shoals Medical Group, LLC, submitted 17,104 claims for payment to the Centers for Medicare & Medicaid Services (CMS) contractors using Healthcare Common Procedure Coding System (HCPCS) code G0434; the claims were excess and false in that they were claims for multiple tests or procedures related to a single patient encounter or a single urine sample; further, filing a claim for more than one test or procedure related to a

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[1] The parties refer to Mohammad Siddique, M.D. and Shoals Medical Group, LLC, as Petitioners and that was the way the case was initially docketed. Pursuant to 42 C.F.R. § 1005.2(b), in an exclusion case the parties are the petitioner and the Inspector General of the U.S. Department of Health and Human Services (I.G.). However, in a case involving a civil money penalty (CMP), the parties are the I.G. and the respondent. Because a CMP is involved in this case, the style of the case was corrected by the Prehearing Scheduling Order dated November 19, 2015, para. X.A., to refer to the parties as the I.G. versus Respondents.

single patient encounter or a single urine sample violated the published policy of the Secretary of Health and Human Services (the Secretary). There is a basis for the imposition of sanctions pursuant to section 1128A(a)(1)(A) and (B) of the Social Security Act (the Act) (42 U.S.C. §§ 1320a-7(a)(1)(A) and (B)). A CMP of $1,710,400, an assessment of $1,057,251.67, and exclusion of Respondents from Medicare, Medicaid, and all federal health care programs for ten years are reasonable sanctions.[2]

I. Background

The I.G. notified Respondents by letter dated August 21, 2015 (Proposed Determination), that he intended to impose against Respondents an assessment of $1,195,215.13 and a CMP of $1,710,400.00, for a total penalty of $2,905,615.13. The I.G. also advised Respondents that he intended to exclude them from participation in all federal health care programs for a minimum of ten years.[3] The I.G. cited as authority sections 1128A(a)(1)(A) and (B) of the Act. The I.G. alleged that between October 13, 2011 and November 6, 2012, Respondents submitted 17,104 claims for payment under HCPCS code G0434 totaling $505,521.30, where each claim was for more than one urine test per patient encounter when only one such test was generally allowed to be billed under HCPCS code G0434. The I.G. alleged that Respondents' conduct amounted to the knowing presentation to an agent of Medicare, claims for services that Respondents knew or should have known were either not provided as claimed or were false or fraudulent. The I.G. further alleged that Respondents avoided claim reviews by appending a modifier to each claim that indicated that the claim was for a separate patient encounter. The I.G. proposed an assessment of three times the amount billed in lieu of damages due to the false claims, a total of $1,516,563.90, which was reduced to $1,195,215.13 by crediting a prior payment made by Respondents. The I.G. proposed a CMP of $100 for each of the 17,104 excess claims filed by Respondents.

Petitioner timely requested a hearing through counsel on September 15, 2015 (RFH). On October 26, 2015, the case was assigned to me to hear and decide. I convened a

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[2] The term "sanctions" refers collectively to the penalties involved, including the CMP, assessment, and exclusion authorized by the Act and 42 C.F.R. pt. 1003.

[3] Pursuant to 42 C.F.R. § 1003.135, Respondents may apply for reinstatement only after the period of exclusion expires. Reinstatement is not automatic upon completion of the period of exclusion and any request for reinstatement will be considered in accordance with 42 C.F.R. §§ 1001.3001 through 1001.3004. Citations are to the 2014 revision of the Code of Federal Regulations (C.F.R.), unless otherwise stated.

telephone prehearing conference on November 18, 2015, the substance of which is memorialized in my Prehearing Scheduling Order dated November 19, 2015.

On April 18, 2016, the I.G. filed his witness and exhibit lists and I.G. exhibits (I.G. Exs.) 1 through 35. Respondents filed their exhibits (R. Exs.) 1 through 3 on April 18, 2016. On May 5, 2016, the I.G. filed a motion for leave to file I.G. Ex. 36 and an unmarked audio recording that I treat as I.G. Ex. 37. On May 16, 2016, Respondents filed a motion to exclude evidence offered by the I.G. that I discuss hereafter. The I.G. responded to the motion on May 25, 2016.

On May 17, 2016, the parties filed a joint status report and request to resolve this case on the documents (JSR & Waiver of Hearing), with both parties affirmatively waiving an oral hearing. I conclude that the parties who are represented by counsel knowingly waived the right to cross-examine witnesses by their waivers of oral hearing. The parties filed their briefs on May 17, 2016 (I.G. Br. and R. Br., respectively). The I.G. filed a reply brief on June 9, 2016 (I.G. Reply) and Respondents filed a reply brief on July 1, 2016 (R. Reply). The I.G. failed to mark and file a copy of the Proposed Determination as an exhibit. Petitioner filed a copy of the I.G. notice with the request for hearing (DAB E-File Item #1a) and that document is treated as if marked Court Exhibit (Ct. Ex.) 1, which is admitted as evidence.[4]

On May 16, 2016, Respondents filed a "Motion to Exclude Redundant and Irrelevant Information" (Motion to Exclude) that referred to both proposed witnesses and documentary evidence. Respondents argue that the only issue in this case is Respondents' scienter, that is, state of mind, and they further argue that there are no issues of fact related to the filing of claims or that the claims were improperly filed, rendering irrelevant many of the I.G.'s offered documents and witnesses. Respondents correctly acknowledge that I am tasked to determine the admissibility of evidence. The Federal Rules of Evidence are not binding but may be applied where appropriate. I am required to exclude irrelevant or immaterial evidence. I may exclude evidence that is more prejudicial than probative or that may cause confusion, needless delay, or the presentation of cumulative evidence. Privileged evidence must be excluded even if relevant. Evidence of offers in compromise is generally inadmissible. Evidence of crimes, wrongs, or acts other than those for which Respondents are charged may be considered for limited purposes. 42 C.F.R. § 1005.17(a)-(g). Respondents' objections to

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[4] Generally, the I.G. should, out of an abundance of caution, anticipate possible notice issues and, recognizing the need to prove adequate notice, offer as exhibits copies of any notices required to be issued by regulation or the Act.

witnesses are moot based on the parties' waivers of oral hearing in this case. JSR & Waiver. Respondents argue that I.G. Exs. 24, 25, 27, 28, 29, 30, and 31, which include detailed claims data, are irrelevant because they are not disputing the claims or that they were improperly filed. The objection is overruled. Although Respondents concede the filing of the claims, the claims data may nevertheless be relevant to the issue of the reasonableness of the sanctions proposed by the I.G. if liability is found. Petitioner has not specifically waived the issue of whether the proposed sanctions are reasonable and has characterized the sanctions in various pleadings as being unreasonable. Respondents object to I.G. Exs. 14 and 16. Respondents argue that these exhibits – which tend to show agency between Respondents and its billing companies – are not relevant to scienter and may be more prejudicial than probative. Whether or not Respondent Siddique was pleasant in his dealings with his billing companies is completely irrelevant and not appropriate to consider, and I do not consider that aspect of the documents. The existence of agency with billing companies may have some minimal relevance to both scienter and the reasonableness of the sanctions, if liability is found. Accordingly, Respondents' objections are overruled. Respondents object to I.G. Exs. 4, 5, 6, 7, 8, and 10, on grounds they are not relevant to scienter. While I.G. Exs. 4, 5, 6, 7, 8, and 10 may not be relevant to show Respondents' state of mind, they certainly are relevant to show the state of Respondents' knowledge and are admissible. Respondents in their reply brief acknowledged that, to the extent the I.G.'s evidence may be considered on the issue of the reasonableness of the proposed sanctions, Respondents withdrew the relevancy objection. P. Reply at 21.

The I.G. did not specifically object to R. Exs. 1, 2, and 3. The I.G. argued that R. Ex. 1, a transcript of an audio recording, was not reliable or accurate. Therefore, the I.G. offered the actual audio recording (DAB E-File Item #20), which I treat as I.G. Ex. 37. I have compared R. Ex. 1 and I.G. Ex. 37 and find only non-substantive differences between the transcript and the actual recording. The conversation recorded in R. Ex. 1 and I.G. Ex. 37 clearly occurred after Respondent Siddique filed the claims in issue and he was on notice that he was under investigation. While the recording is arguably self-serving, that argument goes to the weight of the evidence and not its admissibility. The recording is not sworn testimony and may not be treated as such. 42 C.F.R. § 1005.16(a). The recording and transcript is relevant to scienter and knowledge and the issue of the reasonableness of the sanctions proposed. The I.G. argues that R. Exs. 2 and 3 are not in the form of declarations or otherwise supported by a declaration or affidavit. R. Exs. 2 and 3 are merely attempts to authenticate the recording as transcribed. Because the I.G. offered the recording as evidence, the I.G. waived any objection as to the authenticity of the recording and R. Exs. 2 and 3 are unnecessary. Accordingly, I.G. Exs. 1 through 37 and R. Ex. 1 are admitted as evidence.

The issues have been joined and this case is now ripe for decision.

II. Discussion

A. Applicable Law and Jurisdiction

Congress granted the Secretary authority to impose CMPs in varying amounts, assessments in lieu of damages, damages, and to exclude from Medicare any person, organization, agency, or other entity who committed any of the acts described in section 1128A(a) or (b) of the Act. Act § 1128A(a), (b) (42 U.S.C. § 1320a—7a(a), (b)). Pursuant to 1128A(c)(1), the Secretary may initiate a proceeding to determine whether or not to impose a CMP, assessment, or exclusion pursuant to section 1128A(a) or (b) only as authorized by the Attorney General. Respondents do not question whether the Attorney General has authorized the imposition of sanctions against them. The Secretary may not initiate an action more than six years after the date of the claim, request for payment, or other occurrence that is the basis for the action under section 1128A(a) or (b). Act § 1128A(c)(1). Respondents do not argue that this action is time-barred.

The Secretary may not make an adverse determination to impose a CMP, assessment, or exclusion under section 1128A(a) or (b) until the target of the action has been given written notice and an opportunity for a hearing on the record. Act § 1128A(c)(2). In determining the amount of any CMP, assessment or exclusion, the Secretary must consider: (1) the nature of the claims and the circumstances under which they were presented; (2) the degree of culpability, history of prior offenses, and financial condition of the target; and (3) such other matters as justice may require. Act § 1128A(d).

A person, organization, agency, or other entity subject to an adverse action pursuant to section 1128A(a) or (b) of the Act has a right to review in the U.S. Circuit Court of Appeals in the circuit where the person resides or the organization, agency, or other entity is located or in which the claims that are the basis for the action were presented. Act § 1128A(e).

Congress authorized the Secretary to delegate the authority granted by section 1128A(a) and (b) of the Act to the I.G. Act §1128A(j)(2). The Secretary has promulgated regulations implementing section 1128A of the Act at 42 C.F.R. pt. 1003 and delegated authority under the Act to the I.G. 42 C.F.R. § 1003.102.

A person subject to a proposed penalty, assessment, or exclusion has a right to review by an administrative law judge (ALJ) and appeal to the Departmental Appeals Board (the Board) in accordance with 42 C.F.R. pt. 1005. 42 C.F.R. § 1003.109(b). Absent a timely request for hearing, a proposed penalty, assessment, or exclusion becomes final and not subject to further review. 42 C.F.R. §§ 1003.109(c) – .110.

A person sanctioned under 42 C.F.R. pt. 1003 has a right to request a hearing before an ALJ. 42 C.F.R. § 1005.2(a). Pursuant to 42 C.F.R. § 1005.15(a), a hearing on the record

is required to determine whether a respondent is subject to a sanction, unless both parties waive appearance at an oral hearing and elect to submit only documentary evidence and written argument as authorized by 42 C.F.R. § 1005.6(b)(5). In a CMP case under 42 C.F.R. pt. 1003, a respondent bears the burden of going forward and the burden of persuasion with respect to affirmative defenses and any mitigating factors, and the I.G. bears the burden with respect to all other issues. 42 C.F.R. § 1005.15(b). The burden of proof in an exclusion case that also involves a CMP is the same. 42 C.F.R. § 1005.15(c). A preponderance of the evidence is necessary to meet the burden of persuasion. 42 C.F.R. § 1005.15(d).

B. Issues

Whether there is a basis for the imposition of a CMP;

Whether there is a basis for the imposition of an assessment;

Whether there is a basis for excluding Respondents from participating in Medicare, Medicaid, and all other federal health care programs; and

Whether the sanctions proposed by the I.G. are reasonable or adjustment of the sanctions is necessary.

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

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

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[5] "Credible evidence' is evidence that is worthy of belief. *Black's Law Dictionary* 596 (8th ed. 2004). The "weight of evidence" is the persuasiveness of some evidence compared to other evidence. *Id*. at 1625.

1. Between April 3, 2011 and September 27, 2012, Respondents submitted 17,104 claims under HCPCS code G0434, which were improper claims because each exceeded the limit of one claim authorized under HCPCS code G0434 per patient encounter or one test per urine sample collected on a date of service.[6]

2. Respondents were improperly paid $351,666.78 on claims for the excess units that totaled $459,533.48.

3. Respondents are liable for the acts of their agents, including their coding and billing specialists, whose acts are within the scope of their agency.

4. Respondents had actual notice[7] of the limitation on filing claims under HCPCS code G0434 based on the Secretary's publication of the adoption of that HCPCS code in the Federal Register as required by section 1871 of the Act (42 U.S.C. § 1395hh) and 44 U.S.C. § 1507.

5. Respondents' purported ignorance of the limitations on filing claims under HCPCS code G0434 is no defense because the notice of the adoption of that code was published in the Federal Register as required by section 1871 of the Act and 44 U.S.C. § 1507.

6. Respondents committed upon enrolling in Medicare to comply with the provisions of applicable statutes, regulations, and program instructions of the Secretary, which includes the coding definition for HCPCS code G0434.

On August 21, 2015, the I.G. gave Respondents notice of the proposed determination to impose a CMP, assessment, and ten-year exclusion. Notice is required by section

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[6] These claims are referred to by the parties and in this decision as "excess claims" due to the fact that they exceed the limitation of one claim per encounter under HCPCS code G0434.

[7] This is referred to as "constructive notice" in the title of 44 U.S.C. § 1507 of the Federal Register Act (44 U.S.C. chap. 15). That section states that, unless otherwise provided by law, filing with the Office of the Federal Register for publication and public inspection is sufficient to give notice of the contents of the document to affected persons.

1128A(c)(2) of the Act and 42 C.F.R. § 1003.109(a). Ct. Ex. 1. Respondents have not challenged the sufficiency of the notice.

The I.G. advised Respondents by the Proposed Determination that he intended to impose a CMP, an assessment, and to exclude both Respondents from participation in all federal health care programs for ten years. Ct. Ex. 1. The I.G. cited sections 1128A(a)(1)(A) and (B) of the Act as the basis for the proposed sanctions. Sections 1128A(a)(1)(A) and (B) subject a person to a CMP, assessment, and exclusion for the following conduct:

> (a) Any person (including an organization, agency, or other entity, but excluding a beneficiary, as defined in subsection (i)(5)) that—
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> > (1) knowingly presents or causes to be presented to an officer, employee, or agent of the United States, or of any department or agency thereof, or of any State agency (as defined in subsection (i)(1)), a claim (as defined in subsection (i)(2)) that the Secretary determines—
> >
> > > (A) is for a medical or other item or service that the person knows or should know was not provided as claimed, including any person who engages in a pattern or practice of presenting or causing to be presented a claim for an item or service that is based on a code that the person knows or should know will result in a greater payment to the person than the code the person knows or should know is applicable to the item or service actually provided,
> > >
> > > (B) is for a medical or other item or service and the person knows or should know the claim is false or fraudulent.

Act § 1128A(a)(1)(A) and (B). Section 1128A(a)(1)(A) authorizes a sanction against a person who submits a claim or caused a claim to be submitted and the person knew or should have known:

- A claim is for an item or service that was not actually provided; or
- He or she is engaging in a pattern or practice of up-coding, i.e., filing a claim using a code that will cause a payment higher than the code that is actually applicable to the item or service actually furnished.

Section 1128A(a)(1)(B) authorizes a sanction against a person who submits a claim or causes a claim to be submitted and the person knows or should know that the claim is false or fraudulent. A "claim" is "an application for payments for items and services" under a federal health care program and includes Medicare, Medicaid, and other health care programs funded in whole or in part by the federal government. Act § 1128(h), 1128(A)(i)(2), 1128B(f). Section 1128A(a)(1) requires that a person knowingly submit or cause to be submitted a claim. The Act defines "should know" as follows:

> The term "should know" means that a person, with respect to information—
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> > (A) acts in deliberate ignorance of the truth or falsity of the information; or
> >
> > (B) acts in reckless disregard of the truth or falsity of the information,
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> and no proof of specific intent to defraud is required.

Act §1128A(i)(7). The Secretary has defined the term "knowingly" by regulation:

> [T]he term "knowingly" is defined consistent with the definition set forth in the Civil False Claims Act (31 U.S.C. § 3729(b)), that is, a person, with respect to information, **has actual knowledge of 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 that no proof of specific intent to defraud is required.

42 C.F.R. § 1003.102(e) (emphasis added). Fraud and fraudulent are not defined under either section 1128A of the Act or 42 C.F.R. pt. 1003. Fraud has several definitions depending upon the context. A general legal definition for fraud is a "knowing misrepresentation of the truth or concealment of a material fact to induce another to act to his or her detriment." *Black's Law Dictionary* 685 (8th ed. 2004). Fraud may also be a "misrepresentation made recklessly without belief in its truth to induce another person to act." *Id*. Fraudulent is the adjectival form of the term fraud. "A principal is liable for penalties, assessments, and an exclusion under this section for the actions of the principal's agent acting within the scope of the agency." Act § 1128A(*l*).

Respondents do not dispute that the claims at issue in this matter were submitted to the CMS Medicare contractor for payment by various agents that Respondents used for billing and collections. I.G. Exs. 12-17; R. Br. at 2, 6. Respondents do not dispute that

they knowingly caused the 17,104 claims to be submitted by their billing agents. R. Br. at 2, 4. Respondents argue, rather, that they did not know they could not submit claims using HCPCS code G0434 for multiple tests conducted from a single urine sample. RFH; R. Br. at 3-7. As discussed in greater detail hereafter, Respondents' purported "ignorance of the law furnishes no excuse for any mistake or wrongful act." *Hawkins v. United States*, 96 U.S. 689, 691 (1877).

a. Facts

It is not disputed that prior to January 1, 2011, Respondents were permitted to file multiple claims for multiple tests or procedures, including separate tests for multiple drugs of abuse, conducted upon a single urine sample obtained during a single patient encounter. I.G. Exs. 4-5.

It is not disputed that on November 19, 2010, CMS posted to its website the 2011 Calendar Year "New Clinical Laboratory Fee Schedule Test Codes and Final Payment Determinations," which listed new HCPCS code G0434 and explained that for any "patient encounter, no matter how many drugs of abuse tests are performed . . . proper billing would be one time per patient." I.G. Exs. 7 at 5; 35 at 2 ¶7.

Ten days later, on November 29, 2010, the Secretary published the annual update of the list of CPT[8]/HCPCS codes in the Federal Register, giving notice that HCPCS code G0434 was added to the list of CPT/HCPCS Codes. 75 Fed. Reg. 73,170, 73,584 (Nov. 29, 2010).

On February 14, 2011, CMS issued a Medicare Learning Network "MLN*Matters*,"[9] #SE1105, which explained that: "[o]nly one unit of service for code G0434 can be billed

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[8] Common Procedural Terminology (CPT®) codes are maintained by the American Medical Association. HCPCS (commonly referred to as "hick picks") codes are established and maintained by CMS and used primarily to identify products, supplies, and services not included under the CPT codes.

[9] At the bottom of each page of the MLN*Matters* appears the following disclaimer:

> This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take

(Footnote continued next page.)

per patient encounter regardless of the number of drug classes tested and irrespective of the use or presence of the QW modifier on claim lines." I.G. Exs. 10 at 3; 34 at 2 ¶7.

The I.G. alleges in the Proposed Determination and his briefs that Respondents submitted more than one claim related to one patient encounter for urine testing under HCPCS code G0434. The I.G. alleges that only one claim may be billed using HCPCS code G0434 per patient encounter and urine sample, subject to limited exceptions not applicable in this case, regardless of the number of drugs the urine is tested for. The I.G. alleges that between October 13, 2011 and November 6, 2012, Respondents submitted claims for multiple tests under HCPCS code G0434 related to single patient encounters. The I.G. alleges that Respondents submitted 17,104 excess claims totaling $505,521.30 during the period October 13, 2011 and November 6, 2012. The I.G. also alleges that Respondents avoided automated claim reviews by appending Modifier 59 to many of the 17,104 excess claims for units of HCPCS code G0434. The I.G. alleges that the use of Modifier 59 indicates that each unit claimed was related to a separate patient encounter, office visit, or injury, when in fact, the claims submitted by Respondents or their agents were not related to separate patient encounters. Ct. Ex. 1 at 2-3; I.G. Br. at 2-4, 8-9.

The allegations in the Proposed Determination and in the I.G.'s briefs before me do not conform to the proof offered by the I.G. or the analysis of the I.G.'s Senior Auditor, Clarissa J. Yu. Senior Auditor Yu's analysis of the I.G.'s records shows that Respondents' billing or claims agents submitted 17,104 claims with dates of service between April 3, 2011 and September 27, 2012, for excess units of HCPCS code G0434. Auditor Yu treated as an excess claim any additional claim beyond one per patient per

(Footnote continued.)

> the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents.

The disclaimer clearly reflects that the MLN*Matters* publication is not enforceable as a statement of law, regulation, interpretive rule, or policy. The copy of MLN*Matters* is, nevertheless, relevant as evidence of the CMS action adopting G0434 and efforts to communicate billing limitations to providers and suppliers. MLN*Matters* could be evidence of actual notice to Respondents if there was some additional evidence that Respondents actually received and read the MLN*Matters*, or if they conceded those facts, which they have not.

date of service.[10] Auditor Yu's data analysis shows that Respondents were paid $351,666.78 on claims for the excess units totaling $459,533.48. I.G. Exs. 24 at 8, 21; and 36. I find the declaration of Senior Auditor Yu, who is with the Office of Audit Services, Office of the I.G. (I.G. Ex. 36), to be reliable and credible evidence that is consistent with and supported by the claims data in I.G. Ex. 24 at 8, 21; I.G. Ex. 25 at 9, 28, 52, 99; I.G. Ex. 30 at 38-39; and I.G. Ex. 31 at 60-62. The data supports Auditor Yu's testimony that the claims at issue began with the date-of-service April 3, 2011. I.G. Ex. 36. Further, the claim summary data (I.G. Exs. 25 and 31) supports a finding that Respondents filed multiple claims under HCPCS code G0434 for single patient encounters with single urine samples, only through the date of service September 27, 2012, consistent with Auditor Yu's conclusion (I.G. Ex. 36), and not November 6, 2012 as asserted by the I.G. in briefing. I.G. Br. at 3-4, 9. The claims analysis of Senior Auditor Yu is not disputed by Respondents.

Respondents do not dispute that multiple claims were improperly filed using HCPCS code G0434, as alleged in the Proposed Determination. Respondents assert that the improper filings were identified by Respondents long before the I.G. action to impose sanctions; Respondents did a self-audit; and Respondents repaid all known improper claims at that time. RFH at 3; R. Br at 2; R. Reply at 10, 11. Following is a statement from Respondents' prehearing brief, set forth verbatim due to the significance of the admissions made:

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[10] I rely upon the evidence presented by the I.G. rather than the assertions of counsel in briefs and the allegations of the Proposed Determination. The data actually show multiple claims under HCPCS code G0434 with dates of service as early as January 15, 2011 and February 13, 2011. I.G. Ex. 24 at 12, 16-17. However, those claims are for dates of service prior to February 25, 2011, when CMS issued guidance regarding the limitation of HCPCS code G0434 to one claim per patient encounter. I.G. Ex. 34 at 2 ¶¶ 7-10. Citations to exhibits are unclear or not specific throughout the I.G. brief and those errors and the use of the short-form "*id.*" make it extremely difficult to follow the I.G.'s arguments. There is also a lack of clarity as to whether references are to the date of service, date of the claim, date the claim was received, or some other date. The organization of the data in the various I.G. exhibits makes it extremely difficult to identify and analyze the 17,104 claims at issue. Counsel are encouraged to use great care in preparing their cases so as not to make the fact finder's job more difficult. A hearing may have made the fact finder's job easier in this case; however, because the dispositive facts are undisputed by Respondents and this case turns on an issue of law, the time and expense of a hearing, even just for receiving oral arguments, would not have been justified where the sole purpose would have been to ease the fact finder's burden.

> During the time of these events, Dr. [Siddique] operated in rural Alabama a small pain clinic named Shoals Medical Group, LLC that was closed in late 2016.
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> When Dr. [Siddique] saw patients, he usually would take a urine sample for testing. A large number of tests can be run on urine. These include specific gravity, pH, existence of proteins, level of glucose, presence of nitrites, Leukocyte esterase (tells the white blood cell count), ketones, existence of casts, or crystals, bacteria, yeast cells or parasites. There is a long list of possible tests, but all we need to know is that Dr. [Siddique] almost always did eleven (11) tests on each patient, and charged Medicare for each test.
>
> Medicare allowed this until January 2011 when it acknowledged that technology had changed. More advanced testing machines could perform eleven tests from a single urine sample. So Medicare decided to pay once for a single test having eleven results, instead of continuing to allow itself to be charged for each test result derived from a single patient urine sample.
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> After this rule change, a provider such as Dr. [Siddique] could legitimately charge only once for each urine test, no matter how many results were obtained.
>
> But instead of following these rules, Dr. [Siddique] billed a large number [sic] claims representing separate charges to Medicare for each test *result* from the same patient. That is, Dr. [Siddique] continued to charge Medicare eleven times for urine testing on each patient.
>
> A recovery audit contractor (RAC) soon identified this problem. Dr. [Siddique] followed the guidance of the RAC, discontinued this discredited practice of billing, and paid back all of the money the RAC claimed was owed for improperly filed claims.

R. Br. at 2 (emphasis in original). Respondents state in their reply brief that prior to January 2011, billing for multiple tests on a single urine sample from a single patient encounter was the practice. CMS does not dispute this assertion by Respondents. Respondents do not dispute that for an unspecified time after the change in CMS policy in January 2011, Respondents billed only once for each urine sample regardless of the

number of tests performed on that sample. CMS Br. at 16. However, Respondents concede that at some unspecified time after January 2011, Respondents reverted to billing for each separate test performed on a single urine sample. Respondents admit that "many urine tests were [improperly] broken down and a separate claim was made for each result." Respondents concede that all the multiple claims were improper. R. Reply at 11.

b. Analysis

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. Payment under the program for services rendered to Medicare-eligible beneficiaries may only be made to eligible providers of services and suppliers. Act §§ 1835(a) (42 U.S.C. § 1395n(a)); 1842(h)(1) (42 U.S.C. § 1395(u)(h)(1)). Administration of the Part B program is through contractors. Act § 1842(a) (42 U.S.C. § 1395u(a)). The Act requires the Secretary to issue regulations that establish a process for the enrollment in Medicare of providers and suppliers. Act § 1866(j) (42 U.S.C. § 1395cc(j)). Pursuant to 42 C.F.R. § 424.505, providers and suppliers must be enrolled in the Medicare program to be reimbursed for services provided to Medicare beneficiaries. Many clinical laboratory services are covered by Medicare, when properly ordered. Act §§ 1832 (42 U.S.C. § 1395k); 1834 (42 U.S.C. § 1395m(k); 1861 (42 U.S.C. § 1395x(s)(1)). The Medicare program authorizes Medicare Part B payments for clinical laboratory services furnished in accordance with the provisions of the Act and regulations. 42 C.F.R. §§ 410.10(e) and 32(d).

Participation in Medicare imposes obligations upon suppliers such as Respondents. Suppliers must submit complete, accurate and truthful responses to all information requested in the enrollment application. 42 C.F.R. § 424.510(d)(2). Pursuant to 42 C.F.R. §§ 424.502 and 424.510(d)(3), a supplier's application to enroll in Medicare must be signed by an authorized official, i.e. one with authority to bind the provider or supplier both legally and financially. The regulation provides that the signature attests to the accuracy of information provided in the application. The signature also attests to the fact that the provider or supplier is aware of and abides by all applicable statutes, regulations, and program instructions of the Medicare program. 42 C.F.R. § 424.510(d)(3). The Board has recognized that by enrolling in Medicare, a provider or supplier agrees to be bound by Medicare program instructions. *Proteam Healthcare, Inc.*, DAB No. 2658 at 11-12 (2015); *Realhab, Inc.*, DAB No. 2542 at 17, (2013). 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 is no issue in this case that Respondents were enrolled in Medicare as suppliers of clinical laboratory services with a CLIA certificate and a certificate of waiver[11] issued in accordance with 42 C.F.R. pt. 493. I.G. Exs. 1, 2. Respondent Siddique admits that during the period in question he operated Respondent Shoals Medical Group, LLC as a pain clinic providing physician services (R. Br. at 2), though the I.G. has presented no specific evidence of Medicare enrollment other than the CLIA certificate or the date of Respondents' enrollment. The requirements for enrolling in Medicare and the obligations related to participating in Medicare have been substantially the same since 2006. 71 Fed. Reg. 20,776 (Apr. 21, 2006); 73 Fed. Reg. 36,461 (June 27, 2008); 75 Fed. Reg. 50,418 (Aug. 16, 2010); 75 Fed. Reg. 70,464 (Nov. 17, 2010); 75 Fed. Reg. 73,628 (Nov. 29, 2010); 77 Fed. Reg. 29,030 (July 16, 2012).

The gist of the I.G.'s theory is that Respondents either knew or should have known that after January 2011, billing or claiming under HCPCS code G0434 for more than one test from a single urine sample and a single patient encounter using G0434 was false or fraudulent and subject to sanctions under section 1128A(a)(1)(B). The I.G. has not attempted to establish a violation of section 1128A(a)(1)(A) by showing and arguing that the multiple tests for which claims were submitted were not actually performed as claimed. The sanctionable conduct according to the I.G. is Respondents' filing claims for more than one test run on one urine sample. It is undisputed that, for over a year, Respondents submitted 17,104 claims billing for more than one test run on a single sample from a single patient encounter, which is, arguably, a pattern of such claims. Filing multiple claims when only a single claim is authorized also fits roughly within the concept of up-coding under section 1128A(a)(1)(A) to the extent that the coding practice resulted in a higher payment to Respondents for the multiple tests separately claimed than is permitted under HCPCS code G0434. Accordingly, either section 1128A(a)(1)(A) or (B) could be the basis for sanctions in this case.

The I.G.'s primary argument that Respondents knew or should have known it was wrong to file multiple claims for multiple tests on a single urine sample is the fact that Respondents correctly filed claims under HCPCS code G0434 when the change in CMS policy first occurred in January 2011. I.G. Br. at 2-3, 6-9, 16-18. The I.G. urges me to conclude, based on Respondents' conduct that not only did Respondents have actual

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[11] The tests a laboratory may perform under a certificate of waiver are simple laboratory examinations and procedures which use test systems cleared by the Food and Drug Administration for home use; employ methodologies that are so simple and accurate that the risk for error is negligible; or pose no reasonable risk of harm to the patient if the test if performed incorrectly. 42 C.F.R. § 493.15(b).

knowledge of the change to HCPCS code G0434, but that Respondents had actual knowledge of the limitation of one claim per urine sample. The fact that Respondents correctly filed claims after January 1, 2011, clearly shows that Respondents and their billing agents had knowledge of the change by CMS to using HCPCS code G0434. Respondents do not deny actual knowledge of the change. Respondents do deny actual knowledge of the limitation to one claim per urine sample per patient encounter. The fact that Respondents properly filed several claims that billed for only one test per urine sample between January and April 2011, does not support an inference that Respondents had actual knowledge of the limitation of billing for only one test per sample under HCPCS code G0434. Indeed, the fact that Respondents claimed only one test per urine sample may reflect that only one test was actually performed on those samples. There is no evidence derived from interviews of Respondent Siddique or Respondents' billing agents or documentary evidence that shows it was more likely than not that Respondents and their agents had actual knowledge of the limitations on claims under HCPCS code G0434. Given the government's limited evidence, I will not infer based on a few single claims under HCPCS code G0434, that Respondent had actual knowledge of the limits of HCPCS code G0434. However, it is not necessary to rely upon evidence of Respondents' conduct to show actual knowledge of the limitation on claims filed using HCPCS code G0434.

Respondents argue that the issue to be decided in this case is whether Respondent Siddique had the scienter required for the I.G. to impose a CMP, assessment, and exclusion. R. Br. at 3. Respondents argue that it has not been shown that they had the requisite scienter to be sanctioned under section 1128A(a)(1) of the Act. Scienter is a "degree of knowledge that makes a person legally responsible for the consequences of his or her act or omission. . . . " *Black's Law Dictionary* 1373. The scienter requirement of section 1128A(a) for the imposition of a CMP, assessment, and exclusion is whether or not Respondents either knew or should have known that the claims and conduct, i.e., the facts related to those claims, were sanctionable under section 1128A(a)(1)(A) and (B). Respondents argue that the I.G. must show by a preponderance of the evidence that Respondents acted with "deliberate ignorance" when they "allowed the wrongful claims to be filed" or they acted with "reckless disregard of whether or not the claims were proper." R. Br. at 5. Respondents argue they did not act with deliberate ignorance or careless disregard for whether or not the claims were proper. Respondents argue that they relied upon coding and billing specialists for the proper way to bill Medicare. R. Br. at 5. Respondents reason that because they sought and relied upon the advice of experts there was no reckless disregard or deliberate ignorance of the truth or falsity of claims. RFH; R. Br. at 6. Respondents also argue that as soon as the problem was identified they did a self-audit; identified improper claims; and promptly repaid $350,000, which resulted in the Recovery Audit Contractor closing the audit. R. Reply at 1. Respondents argue that I should not infer, but must find from the evidence that Respondents either knew or should have known that the claims were improper. Respondents assert that I may not infer reckless disregard from circumstantial evidence. R. Reply 4-5, 7, 19. In

short, Respondents' defense is that they neither knew nor should have known that the practice of billing under HCPCS code G0434 for multiple tests on a single urine sample and a single patient encounter was improper, wrong, false, or fraudulent. R. Br. Respondents' argument in this case is really an argument that they were "ignorant of the law" as it related to HCPCS code G0434. Respondents' defense fails as a matter of law.

Respondents state in their brief: "[i]f the trier of fact finds that [Respondents] 'knew or should have known' that the filing of approximately 17,000 improper claims was wrong, then this appeal is lost." R. Br. at 4. I conclude that the Respondents and their agents had actual knowledge that after January 2011 and through September 2012, submitting multiple claims for multiple tests on a single urine sample from a single patient encounter using HCPCS code G0434 was prohibited. It is not necessary to resolve issues related to the use of Modifier 59, as the improper claims are a basis for sanctions with or without consideration of the alleged improper use of Modifier 59.

Executive branch agencies are required to make available to the public "substantive rules of general applicability adopted as authorized by law, and statements of general policy or interpretations of general applicability formulated and adopted by the agency; and each amendment, revision, or appeal of the foregoing." 5 U.S.C. § 552(a)(1)(D)-(E).[12]

> Except to the extent that a person has actual and timely notice of the terms thereof, a person may not in any manner be required to resort to, or be adversely affected by, a matter required to be published in the Federal Register and not so published. For the purpose of this paragraph, matter reasonably available to the class of persons affected thereby is deemed published in the Federal Register when incorporated by reference therein with the approval of the Director of the Federal Register.

5 U.S.C. § 552(a)(1).

The Act requires that the Secretary "prescribe such regulations as may be necessary to carry out the administration of [Medicare]." Act § 1871(a)(1). The Act further provides:

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[12] This section of the Administrative Procedure Act (5 U.S.C. §§ 551-59) is popularly known as the Freedom of Information Act.

> No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this title shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1)[Act § 1871(a)(1)].

Act § 1871(a)(2). The Secretary is required to publish in the Federal Register, "not less frequently than every 3 months, a list of all manual instructions, interpretative rules, statements of policy, and guidelines of general applicability" that are not promulgated as regulations. Act § 1871(c)(1).

On November 29, 2010, the Secretary published the annual update of the list of CPT/HCPCS codes in the Federal Register, giving notice that G0434 was added to the list of CPT/HCPCS Codes. 75 Fed. Reg. 73,170, 73,584 (Nov. 29, 2010). Respondents have not disputed the adequacy of the notice or that it fully complied with the requirements of 5 U.S.C. § 442 and Act § 1871(a) and (c). By virtue of publication in the Federal Register, Respondents had actual knowledge of the adoption of HCPCS code G0434. 44 U.S.C. §§ 1505(a), 1507; 1 Admin. L. & Prac. § 4:46 (3d ed. 2016). Although the limitations on claims under HCPCS code G0434 were not explained in detail in the Federal Register notice, CMS published the limitations both before and after the publication of the adoption of HCPCS code G0434 in the Federal Register. Respondents have not disputed the I.G.'s evidence which shows that the full description for HCPCS code G0434 was published on the CMS website so that it was available to Respondents and their agents for accurate coding. Respondents have also not disputed that the limitations upon claims under HCPCS code G0434 were also provided to suppliers through MLN*Matters*. I.G. Exs. 7 at 5; 10 at 2-3; 34 at 2 ¶7; 35 at 2 ¶7. Respondents have not denied their regulatory duty to comply with pertinent statutes, regulations, and program instructions.

I conclude that Respondents conceded knowledge of the facts related to the 17,104 claims. I conclude that Respondents had actual knowledge of the adoption of HCPCS code G0434 through publication as required by the Act in the Federal Register. Further, the limitations related to using HCPCS code G0434 were provided by CMS through other resources such as the CMS website and MLN*Matters*. Accordingly, I conclude that Respondents had all the knowledge required to be subject to sanction pursuant to section 1128A(a) of the Act.

7. A CMP of $1,710,400, an assessment of $1,057,251.67, and exclusion of Respondents for a minimum of ten years are reasonable sanctions.

I have concluded that there is a basis for the impositions of sanctions against Respondents. Therefore, it is necessary to determine reasonable sanctions.

The Act authorizes a CMP of $10,000 for each claim subject to section 1128A(a)(1); an assessment in lieu of damages of no more than three times the amount claimed; and exclusion from participation of federal health care programs as defined by section 1128B(f)(1) of the Act. The Secretary has delegated authority to the I.G. by regulation to impose a CMP of $10,000 for each claim subject to 1128A(a) of the Act and 42 C.F.R. § 1003.102(a). 42 C.F.R. § 1003.103(a)(2). The Secretary authorized the I.G. to impose an assessment in lieu of damages of three times the amount for each item or service wrongfully claimed that is subject to section 1128A(a) of the Act and 42 C.F.R. § 1003.102(a). 42 C.F.R. § 1003.104(a)(2). Additionally, the Secretary has authorized exclusion from participation in Medicare, Medicaid, and all federal health care programs of a person or entity subject to a CMP or assessment under 42 C.F.R. § 1003.102(a). 42 C.F.R. § 1003.105(a)(1)(i).

Section 1128A(d) of the Act requires consideration of the following factors in determining the amount of CMP or assessment and the duration of an exclusion:

1. Nature of claims and circumstances under which they were presented;

2. Degree of culpability, history of prior offenses, and financial condition of the person presenting the claims; and

3. Other matters as justice may require.

The Secretary has required by regulation the consideration of certain factors, and the following are applicable to this case:

1. Nature of the claims or other wrongdoing;

2. Degree of culpability;

3. History of prior offenses;

4. Financial condition; and

5. Such other matters as justice may require.

42 C.F.R. § 1003.106(a)(1). In 42 C.F.R. § 1003.106(b), the Secretary has established guidelines for considering the factors established by 42 C.F.R. § 1003.106(a)(1). The factors established by 42 C.F.R. § 1003.106(a) are also considered with respect to whether to exclude and the duration of such exclusion. 42 C.F.R. § 1003.107(a).

The I.G. notified Respondents in the Proposed Determination that he intended to impose an assessment of $1,195,215.13 and a CMP of $1,710,400, a total of $2,905,615.13, and to exclude them for ten years. Ct. Ex. 1. The I.G. proposed an assessment of three times the amount billed for each service in lieu of damages due to the false claims, a total of $1,516,563.90, which was reduced to $1,195,215.13 by crediting a prior payment of $321,348.77 made by Respondents. The I.G. proposed a CMP of $100 for each of the 17,104 excess claims filed by Respondents. The I.G. stated in the Proposed Determination that he considered, pursuant to 42 C.F.R. §§ 1003.106 and 1003.107, that Respondents' clams were submitted over a lengthy period of time and that the amount claimed was substantial. The period that the I.G. found was October 13, 2011 to November 6, 2012, just less than 13 months. The I.G. found that the claims totaled $505,521.30. Ct. Ex. 1.

Respondents have not specifically challenged the reasonableness of the CMP, the assessment, the exclusion, or the duration of the exclusion. Respondents have generally alleged that the sanctions proposed by the I.G. are unreasonable. RFH, P. Br. at 4, P. Reply at 5, 20.

Respondents appear to have misconstrued 42 C.F.R. § 1005.4(c)(7) to preclude my review of the reasonableness of the CMP, assessment, and exclusion. P. Br. at 4. The regulation actually provides only that I may not review the exercise of discretion by the I.G. to impose a CMP, assessment, or exclusion under 42 C.F.R. pt. 1003. Section 1005.4(c)(7) of 42 C.F.R. does not preclude ALJ review as provided by section 1128A(c)(2) of the Act and 42 C.F.R. § 1003.109(b) of the proposed CMP, the assessment, and exclusion pursuant to 42 C.F.R. pt. 1005. Section 1005.4(c)(7) of 42 C.F.R. does not affect my authority under 42 C.F.R. § 1005.20(b) to affirm, increase, or reduce the penalties, assessment, or exclusion proposed by the I.G.

The I.G. evidence shows that some adjustment of the assessment is required. According to Senior Auditor Yu, Respondents:

1. Filed 17,104 claims for excess units under HCPCS code G0434;

2. During the period from April 3, 2011 through September 27, 2012, just less than 18 months; and

3. The improper claims submitted totaled $459,533.48.

I.G. Ex. 36 at 1.

The I.G. proposed an assessment of three times the amount of the improper claims. Three times the amount of the improperly filed claims proven by the I.G. before me

yields $1,378,600.44, which when reduced by Respondents' prior payment of $321,348.77, amounts to $1,057,251.67, rather than $1,195,215.13 as determined by the I.G. in the Proposed Determination.

The filing of improper claims occurred over a period of just less than 18 months rather than 13 months as found by the I.G. in the Proposed Determination. My finding that the total number of improper claims was 17,104 is no different from the I.G.'s finding. A CMP of $100 per improper claim amounts to a total CMP of $1,710,400, which is the CMP proposed by the I.G.

I have considered the factors required by section 1128A(d) of the Act and 42 C.F.R. §§ 1003.106(a)(1) and 1003.107(a); and the guidelines under 42 C.F.R. § 1003.106(b). I conclude that the adjusted assessment, CMP, and ten-year exclusion are reasonable sanctions. Respondents do not dispute that their agents filed 17,104 claims using HCPCS code G0434 for multiple tests of single urine samples based on single patient encounters. Respondents offer no excuse for the improper claims except that they were ignorant of the law, i.e., the prohibition on filing multiple claims for multiple tests on one urine sample from a single patient encounter under HCPCS code G0434. The Secretary properly published the adoption of HCPCS code G0434 in the Federal Register which constituted actual knowledge for providers and suppliers of the requirements and limitation of HCPCS code G0434. Therefore, Respondents' asserted ignorance is no excuse. Respondents as enrolled suppliers are responsible to comply with the statutes, regulations, and properly published program directives. 42 C.F.R. § 424.510(d)(3); *Proteam Healthcare, Inc.*, DAB No. 2658; *Realhab, Inc.*, DAB No. 2542. Respondents are culpable for filing thousands of claims over nearly 18 months without ensuring that their agents were filing correct claims. It is undisputed that Respondents did a self-audit and made a voluntary pay back, but only after it was apparent that CMS was examining Respondents' claims. There is no evidence of any prior offenses by Respondents. I do not consider allegations related to use of Modifier 59. Respondents have presented no financial information for my consideration.

III. Conclusion

For the foregoing reasons, Respondents are liable for a CMP of $1,710,400, an assessment of $1,057,251.67, and exclusion from Medicare, Medicaid, and all federal health care programs for a minimum of ten years, all of which are reasonable sanctions.

/s/
Keith W. Sickendick
Administrative Law Judge