Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

PremierTox, Inc.,
(NPI: 1801106620; PTAN: P300031455),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-14-786

Decision No. CR3375

Date: September 19, 2014

DECISION

The Medicare enrollment and billing privileges of Petitioner, PremierTox, Inc., are revoked pursuant to 42 C.F.R. § 424.535(a)(1),[1] effective November 14, 2013.

I. Background

CGS Administrators, LLC (CGS), the Centers for Medicare & Medicaid Services' (CMS) Medicare contractor, notified Petitioner by letter dated October 15, 2013, that its Medicare billing number and billing privileges were revoked effective November 14, 2013. CGS cited 42 C.F.R. § 424.535(a)(1) and (a)(8) as the bases for the revocation. CGS also notified Petitioner that it was subject to a three-year bar to re-enrollment

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[1] Citations are to the 2013 revision of the Code of Federal Regulations (C.F.R.), unless otherwise stated.

pursuant to 42 C.F.R. § 424.535(c). CMS Exhibit (Ex.) 1 at 30-35. On December 12, 2013, Petitioner submitted a request for reconsideration. CMS Ex. 1 at 8-29. On February 11, 2014, a contractor hearing officer issued a reconsidered determination in which she upheld revocation based on 42 C.F.R. § 424.535(a)(1) and (a)(8). CMS Ex. 1 at 1-4.

Petitioner filed a request for hearing (RFH) before an administrative law judge (ALJ) on March 12, 2014. On March 27, 2014, the case was assigned to me for hearing and decision and an Acknowledgement and Prehearing Order (Prehearing Order) was issued at my direction.

On April 28, 2014, CMS filed a motion for summary judgment (CMS Br.), with CMS Exs. 1 through 5. On May 26, 2014, Petitioner filed its opposition to CMS's motion for summary judgment (P. Br.), along with two unmarked exhibits: a document titled "Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and PremierTox 2.0 LLC" (CIA) dated February 7, 2014; and a letter dated May 9, 2014, from Cahaba Safeguard Administrators, LLC (Cahaba) to PremierTox 2.0, Inc. Petitioner failed to mark either document as an exhibit as required by the Prehearing Order ¶ II.D.2 and the Civil Remedies Division Procedures (CRDP) § 9. The CIA is listed in the Departmental Appeals Board Electronic Filing System (DAB e-File) as "Petitioner's Exhibit 1" (P. Ex. 1) and the letter from Cahaba to PremierTox 2.0 Inc. is listed as "Petitioner's Exhibit 2" (P. Ex. 2) in DAB e-File. Because there is little risk for confusion when referring to Petitioner's exhibits, Petitioner was not required to file corrected exhibits and Petitioner's exhibits are referred to as they are listed in DAB e-File. On June 10, 2014, CMS filed a reply.

On July 8, 2014, Petitioner moved to supplement the record with additional argument (P. Supp. Br.). CMS filed a response to Petitioner's supplemental filing on July 17, 2014 (CMS Supp. Response). Petitioner filed a reply on July 18, 2014 (P. Supp. Reply). With its reply, Petitioner submitted an exhibit "Medicare Learning Network, MLN Matters®" Article SE1305 (rev. Feb. 6, 2014) published by CMS. Petitioner also failed to properly mark this document as an exhibit. I treat the document as if marked P. Ex. 3. The parties' supplemental briefings are accepted. No specific objection has been made to any of the offered exhibits and CMS Exs. 1 through 5 and P. Exs. 1 through 3 are admitted as evidence.

II. Discussion

A. Applicable Law

Section 1831 of the Social Security Act (the Act) (42 U.S.C. § 1395j) establishes the supplementary medical insurance benefits program for the aged and disabled known as

Medicare Part B. Administration of the Part B program is through contractors, such as CGS. Act § 1842(a) (42 U.S.C. § 1395u(a)). Payment under the program for services rendered to Medicare-eligible beneficiaries may only be made to eligible providers of services and suppliers.[2] Act §§ 1835(a) (42 U.S.C. § 1395n(a)), 1842(h)(1) (42 U.S.C. § 1395u(h)(1)). Petitioner, a clinical laboratory, is a supplier.

The Act requires the Secretary of Health and Human Services (Secretary) to issue regulations that establish a process for the enrollment in Medicare of providers and suppliers, including the right to a hearing and judicial review of certain enrollment determinations, such as revocation of enrollment and billing privileges. Act § 1866(j) (42 U.S.C. § 1395cc(j)). Pursuant to 42 C.F.R. § 424.505, a supplier such as Petitioner must be enrolled in the Medicare program and be issued a billing number to have billing privileges and to be eligible to receive payment for services rendered to a Medicare-eligible beneficiary.

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. 42 C.F.R. § 424.510(d)(3). Suppliers must meet basic requirements depending on their type of service. 42 C.F.R. §§ 424.505, 424.516, 424.517. Suppliers are also subject to additional screening requirements depending upon the type of service they provide. 42 C.F.R. § 424.518.

The Secretary has delegated the authority to revoke enrollment and billing privileges to CMS. 42 C.F.R. § 424.535. CMS or its Medicare contractor may revoke an enrolled supplier's Medicare enrollment and billing privileges and supplier agreement for any of

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[2] A "supplier" furnishes services under Medicare and includes physicians or other practitioners and facilities that are not included within the definition of the phrase "provider of services." Act § 1861(d) (42 U.S.C. § 1395x(d)). A "provider of services," commonly shortened to "provider," includes hospitals, critical access hospitals, skilled nursing facilities, comprehensive outpatient rehabilitation facilities, home health agencies, hospice programs, and a fund as described in sections 1814(g) (42 U.S.C. § 1395f(g)) and 1835(e) (42 U.S.C. § 1395n(e)) of the Act. Act § 1861(u) (42 U.S.C. § 1395x(u)). The distinction between providers and suppliers is important because they are treated differently under the Act for some purposes.

the reasons listed in 42 C.F.R. § 424.535. Pursuant to 42 C.F.R. § 424.535(a)(1), CMS may revoke a supplier's enrollment and billing privileges if the supplier is determined not to be in compliance with enrollment requirements. If CMS revokes a supplier's Medicare billing privileges, the revocation becomes effective 30 days after CMS or one of its contractors mails the revocation notice to the supplier, subject to some exceptions not applicable in this case. After a supplier's Medicare enrollment and billing privileges are revoked, the supplier is barred from reenrolling in the Medicare program for one to three years. 42 C.F.R. § 424.535(c).

A supplier whose enrollment and billing privileges have been revoked may request reconsideration and review as provided by 42 C.F.R. pt. 498. 42 C.F.R. § 424.545(a). A supplier submits a written request for reconsideration to CMS or its contractor. 42 C.F.R. § 498.22(a). CMS or its contractor must give notice of its reconsidered determination to the supplier, giving the reasons for its determination and specifying the conditions or requirements the supplier failed to meet, and the right to an ALJ hearing. 42 C.F.R. § 498.25. If the decision on reconsideration is unfavorable to the supplier, the supplier has the right to request a hearing by an ALJ and further review by the Departmental Appeals Board (the Board). Act § 1866(j)(8) (42 U.S.C. § 1395cc(j)(8)); 42 C.F.R. §§ 424.545, 498.3(b)(17), 498.5. A hearing on the record, also known as an oral hearing, is required under the Act. *Crestview Parke Care Ctr. v. Thompson*, 373 F.3d 743, 748-51 (6th Cir. 2004). The supplier bears the burden to demonstrate that it meets enrollment requirements with documents and records. 42 C.F.R. § 424.545(c).

B. Issues

Whether summary judgment is appropriate; and

Whether there was a basis for the revocation of Petitioner's billing privileges and enrollment in Medicare.

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

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

1. Summary judgment is appropriate.

CMS has requested summary judgment. A provider or supplier denied enrollment in Medicare or whose enrollment has been revoked has a right to a hearing and judicial review pursuant to section 1866(h)(1) and (j) of the Act and 42 C.F.R. §§ 498.3(b)(1), (5), (6), (8), (15), (17), 498.5. A hearing on the record, also known as an oral hearing, is required under the Act. Act §§ 205(b), 1866 (h)(1) and (j)(8); *Crestview*, 373 F.3d at 748-51. A party may waive appearance at an oral hearing, but must do so affirmatively

in writing. 42 C.F.R. § 498.66. In this case, Petitioner has not waived the right to oral hearing or otherwise consented to decision based only upon the documentary evidence or pleadings. Accordingly, disposition on the written record alone is not permissible, unless the CMS motion for summary judgment has merit.

Summary judgment is not automatic upon request but is limited to certain specific conditions. The Secretary's regulations that establish the procedure to be followed in adjudicating Petitioner's case are at 42 C.F.R. pt. 498. 42 C.F.R. §§ 424.545(a), 498.3(b)(5), (6), (15), (17). The regulations do not establish a summary judgment procedure or recognize such a procedure. However, the Board has long accepted that summary judgment is an acceptable procedural device in cases adjudicated pursuant to 42 C.F.R. pt. 498. *See, e.g.*, *Ill. Knights Templar Home*, DAB No. 2274, at 3-4 (2009); *Garden City Med. Clinic*, DAB No. 1763 (2001); *Everett Rehab. & Med. Ctr.*, DAB No. 1628, at 3 (1997). The Board also has recognized that the Federal Rules of Civil Procedure do not apply in administrative adjudications such as this, but the Board has accepted that Federal Rule of Civil Procedure 56 and related cases provide useful guidance for determining whether summary judgment is appropriate. Furthermore, a summary judgment procedure was adopted as a matter of judicial economy within my authority to regulate the course of proceedings and made available to the parties in the litigation of this case by my Prehearing Order. The parties were given notice by the Prehearing Order that summary judgment is an available procedural device and that the law as it has developed related to Fed. R. Civ. Pro. 56 will be applied.

Summary judgment is appropriate when there is no genuine dispute as to any issue of material fact for adjudication and/or the moving party is entitled to judgment as a matter of law. In determining whether there are genuine issues of material fact for trial, the reviewer must view the evidence in the light most favorable to the non-moving party, drawing all reasonable inferences in that party's favor. The party requesting summary judgment bears the burden of showing that there are no genuine issues of material fact for trial and/or that it is entitled to judgment as a matter of law. Generally, the non-movant may not defeat an adequately supported summary judgment motion by relying upon the denials in its pleadings or briefs but must furnish evidence of a dispute concerning a material fact, i.e., a fact that would affect the outcome of the case if proven. *Mission Hosp. Reg'l Med. Ctr.*, DAB No. 2459, at 4 (2012) (and cases cited therein); *Experts Are Us, Inc.*, DAB No. 2452, at 4 (2012) (and cases cited therein); *Senior Rehab. & Skilled Nursing Ctr.*, DAB No. 2300, at 3 (2010) (and cases cited therein); *see also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

The standard for deciding a case on summary judgment and an ALJ's decision-making in deciding a summary judgment motion differs from that used in resolving a case after a hearing. On summary judgment, the ALJ does not make credibility determinations, weigh the evidence, or decide which inferences to draw from the evidence, as would be done when finding facts after a hearing on the record. Rather, on summary judgment, the

ALJ construes the evidence in a light most favorable to the non-movant and avoids deciding which version of the facts is more likely true. *Holy Cross Vill. at Notre Dame, Inc.*, DAB No. 2291, at 5 (2009). The Board also has recognized that on summary judgment it is appropriate for the ALJ to consider whether a rational trier of fact could find that the party's evidence would be sufficient to meet that party's evidentiary burden. *Dumas Nursing and Rehab., L.P.*, DAB No. 2347, at 5 (2010). The Secretary has not provided in 42 C.F.R. pt. 498, for the allocation of the burden of persuasion or the quantum of evidence required to satisfy the burden. However, the Board has provided some persuasive analysis regarding the allocation of the burden of persuasion in cases subject to 42 C.F.R. pt. 498. *Batavia Nursing & Convalescent Ctr.*, DAB No. 1904 (2004), *aff'd*, *Batavia Nursing & Convalescent Ctr. v. Thompson*, 129 Fed. App'x 181 (6th Cir. 2005).

There is no genuine dispute as to any material fact pertinent to revocation under 42 C.F.R. § 424.535(a)(1) that requires a trial. The issues in this case raised by Petitioner related to revocation under 42 C.F.R. § 424.535(a)(1) are issues of law. The issues in this case must be resolved against Petitioner as a matter of law. The undisputed evidence shows that there is a basis for revocation of Petitioner's Medicare enrollment and billing privileges. Accordingly, summary judgment is appropriate.

Summary judgment is not appropriate for revocation pursuant to 42 C.F.R. § 424.535(a)(8) or the newly articulated bases not considered at the initial or reconsideration levels but urged by CMS for the first time before me. Summary judgment is not appropriate on any of the alternative bases cited by CMS because they involve genuine disputes as to material fact that would require a trial.

2. There is a basis for revocation of Petitioner's Medicare enrollment and billing privileges pursuant to 42 C.F.R. § 424.535(a)(1).

3. Petitioner's enrollment in Medicare and its billing privileges are revoked effective November 14, 2013.

a. Facts

The facts are not disputed and any inferences are drawn in favor of Petitioner.

Petitioner operated a clinical laboratory in Kentucky.[3] Petitioner submitted a Medicare enrollment application (Form CMS-855B) to the Medicare contractor, CGS, dated

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[3] PremierTox, Inc. was organized as a Kentucky Corporation in September 2010, by Brian Walters and James Bottom. Brian Walters and Wes Bottom were the President and

(Footnote continued next page.)

October 15, 2010, that was received by CGS on November 1, 2010. CMS Ex. 2. The application's "Certification Statement" was signed by Brian C. Walters, Petitioner's President on October 15, 2010. CMS Ex. 2, at 18. On the application, Petitioner indicated that it would be submitting its claims for Medicare payment through a billing agency, Liberty Billing, LLC (Liberty).[4] Section 8 of the application clearly informed Petitioner that if it used a billing agency, it was responsible for claims submitted on Petitioner's behalf. CMS Ex. 2 at 12. As part of the application, Petitioner agreed to abide by Medicare laws, regulations, and program instructions. Petitioner acknowledged that the payment of a claim was conditioned upon the underlying transaction being compliant with Medicare law and regulations. CMS Ex. 2 at 17. Petitioner was assigned National Provider Identifier (NPI) 1801106620. CMS Ex. 2 at 23.

CMS and CGS allege that from November 2010 through July 2012, 12,300 Medicare claims for clinical laboratory services provided by Petitioner for Medicare-eligible beneficiaries were submitted by Liberty without the NPI of the physician who ordered the services. CMS and CGS allege that the claims were submitted with Petitioner's own NPI listed as both the "rendering" and the "referring" NPI. CMS Ex. 1 at 6, 30. CMS submitted a list of 98,651 individual claims from March 7, 2011 through May 23, 2012, that list Petitioner's NPI 1801106620 as both the rendering and the referring NPI. I note that the list reflects multiple claims per beneficiary. CMS Ex. 1 at 210-2036. In the initial determination notice dated October 15, 2013, CGS stated that CMS identified 12,300 claims submitted between November 1, 2010 and July 1, 2012. CMS Ex. 1 at 30. CMS does not explain to me why there are different periods and total claims referred to in the October 15 notice and the compilation at CMS Ex. 1 at 210-2036. CMS Br. at 8 n.4. But Petitioner has not disputed the allegation as to 12,300 claims listed in the October 15 notice.

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(Footnote continued.)

Vice Chairman, respectively. CMS Ex. 4. On October 17, 2011, PremierTox, Inc. merged with and into PremierTox 2.0, also a Kentucky corporation, with only PremierTox 2.0 surviving. The merger agreement provided that it constituted a plan of reorganization under the Internal Revenue Code. All properties of PremierTox transferred to PremierTox 2.0. Brian Walters signed the merger agreement as President of PremierTox, Inc. and PremierTox 2.0, Inc. CMS Ex. 5. According to the evidence, James Bottoms and Brian Walters were owners of PremierTox and they also had ownership interests in PremierTox 2.0 with Robert Bertram, Eric Duncan, Robin Peavler, and Bryan Wood. CMS Ex. 1 at 2041. None of these facts have been disputed by Petitioner.

[4] In 2011, Liberty Billing's assets were transferred to another entity known as Liberty Billing 2.0, LLC. CMS Br. at 8 n. 3; CMS Ex. 1, at 134-35, CMS Ex. 3. This fact is of no consequence to this decision, and I use "Liberty" to refer to both entities.

Petitioner admits that Liberty submitted claims on Petitioner's behalf to Medicare for payment that omitted the NPI for the physician or other authorized individual who ordered laboratory services. Petitioner alleges that it had no knowledge of the errors of Liberty until it was notified of the revocation of its billing privileges and Medicare enrollment. RFH at 5-6; P. Br. at 3-7, 9; P. Supp. Br. at 1; CMS Ex. 1 at 11-14, 17, 19. Petitioner submitted a Corrective Action Plan (CAP) that was not accepted by CMS. RFH at 5, 7; P. Br. at 4, 10, 15-16, 20-21; CMS Ex. 1 at 10-14, 20-21, 25-27.

b. Analysis

The requirements for establishing and maintaining Medicare billing privileges are found in 42 C.F.R. pt. 424, subpt. P. Pursuant to 42 C.F.R. § 424.535(a)(1), CMS may revoke an enrolled supplier's Medicare billing privileges and supplier agreement if:

> (1) *Noncompliance*. The provider or supplier is determined not to be in compliance with the enrollment requirements described in this section, or in the enrollment application applicable for its provider or supplier type . . . .

42 C.F.R. § 424.535(a)(1). Petitioner is entitled to receive payment for clinical laboratory services it provided to Medicare-eligible beneficiaries if the services were ordered by a physician or another eligible provider. 42 C.F.R. § 424.507(a)(1)(i). The claim for payment for clinical laboratory services must include the legal name and the NPI of the physician or eligible professional who ordered the services. 42 C.F.R. § 424.507(a)(1)(ii). To enroll and maintain enrollment in Medicare, Petitioner had to comply with all regulatory requirements applicable to a supplier that is a clinical laboratory. 42 C.F.R. § 424.516(a)(2). As a clinical laboratory, Petitioner was required to maintain documents related to services provided to Medicare-eligible beneficiaries for seven years, including written and electronic documents showing the NPI of the ordering physician or other eligible professional relating to orders and certifications and requests for payments. 42 C.F.R. § 424.516(f)(1).

Section 8 of Petitioner's Medicare enrollment application (Form CMS-855B) clearly informed Petitioner that, if it used a billing agency, it was responsible for claims submitted on Petitioner's behalf. CMS Ex. 2 at 12. Petitioner also agreed in the application to abide by Medicare laws, regulations, and program instructions. Petitioner also acknowledged in the application that the payment of a claim was conditioned upon the underlying transaction being compliant with Medicare law and regulations. CMS Ex. 2 at 17.

It is undisputed that Liberty Billing submitted claims to Medicare on Petitioner's behalf and those claims violated the regulatory requirement to list the ordering physician's or eligible professional's NPI on the claim. Therefore, the claims violated Medicare

regulations which govern Medicare enrollment and requirements for Medicare payment, requirements with which Petitioner agreed to comply upon enrollment.

Section 424.535(a)(1) of Title 42 C.F.R. requires that Petitioner be permitted to submit a plan of corrective action. The regulation provides that "[a]ll providers and suppliers are granted an opportunity to correct the deficient compliance requirement before a final determination to revoke billing privileges" except for certain bases for revocation not implicated in this case. 42 C.F.R. § 424.535(a)(1). The October 15, 2013 notice of initial determination advised Petitioner of the right to submit a CAP and to request reconsideration. CMS Ex. 1 at 31. Petitioner submitted a CAP and request for reconsideration. CMS Ex. 1 at 8-29, 33-207. Revocation was upheld on reconsideration and the CAP was apparently found not acceptable inasmuch as CMS persists with the revocation action before me. CMS Ex. 1 at 1-4.

Petitioner argues that the failure of CGS and CMS to accept Petitioner's CAP was in error. RFH at 5, 7. However, the refusal of CMS or its contractor to accept Petitioner's CAP is not an initial determination subject to my review. 42 C.F.R. §§ 405.809, 424.545(a), 498.3(b); *Conchita Jackson, M.D.*, DAB No. 2495 at 5-7 (2013); *Pepper Hill Nursing & Rehab. Ctr., LLC*, DAB No. 2395 at 9 (2011); *DMS Imaging, Inc.*, DAB No. 2313 at 5-8 (2010). Petitioner cites no authority to the contrary.

Petitioner argues that the billing errors involved were solely the fault of Liberty, and should not be attributed to Petitioner, who was unaware of the company's misconduct. P. Br. at 3-11. Petitioner contends that "issues of material fact exist with regard to provider control over the billing company and knowledge of any billing company wrongdoing." P. Br. at 22. I accept as true for purposes of summary judgment that Petitioner had no actual knowledge of Liberty's erroneous listing of Petitioner's NPI as the referring NPI. However, Petitioner is nevertheless ultimately responsible, both as a matter of law and under the terms of its participation agreement, for ensuring that its claims for Medicare reimbursement were accurate and for any errors in those claims. *Louis J. Gaefke, D.P.M.*, DAB No. 2554 at 5-6 (2013). Petitioner cannot avoid responsibility for its claims by the simple expedient of shifting responsibility and liability by contracting with a billing agent. I also accept as true for purpose of summary judgment Petitioner's assertion that there was no evidence of fraud. But Petitioner cites no authority for the proposition that the absence of fraud or fraudulent intent relieves Petitioner of its responsibility for its Medicare claims. Petitioner also argues that it was in substantial compliance citing 42 C.F.R. § 488.301. Petitioner has not shown that the concept of "substantial compliance" as defined in 42 C.F.R. § 488.301, has any application in this case. The cited regulation is found in 42 C.F.R. pt. 488, subpt. E, which sets forth the procedures for the survey and certification of long-term care facilities. Petitioner is a clinical laboratory not a long-term care facility. Furthermore, the revocation in this case is not based on survey and certification, which for clinical laboratories is governed by 42 C.F.R. pt. 493.

Petitioner argues that it merged with PremierTox 2.0, which was permitted to enter a CIA with the Inspector General (IG) for the Department of Health and Human Services (HHS). Petitioner reasons that because PremierTox 2.0 is now in good standing with HHS, the principle of collateral estoppel should apply to preclude revocation of Petitioner's enrollment and billing privileges.[5] P. Br. at 7, 23. Petitioner claims that it "should be treated in the same manner" as PremierTox 2.0. P. Br. at 23.

Petitioner's collateral estoppel argument is meritless. The events that took place between PremierTox 2.0 and the IG have no bearing on the issue of whether there is a basis for the revocation of Petitioner's billing privileges and enrollment in Medicare. In examining the doctrine of collateral estoppel, the Board has noted that collateral estoppel, which is also known as "issue preclusion," is defined as "[t]he binding effect of a judgment as to matters actually litigated and determined in one action on later controversies between the parties involving a different claim from that on which the original judgment was based" and "[a] doctrine barring a party from relitigating an issue determined against that party in an earlier action, even if the second action differs significantly from the first one." *Gregory J. Salko, M.D.*, DAB No. 2437, at 6 (2012) (citing *Black's Law Dictionary* (9th ed. 2009)). Petitioner has not shown that there was any litigation that resulted in a judgment that should have binding effect upon the government in this proceeding. If I construe Petitioner's argument to be equitable in nature, such as equitable estoppel, it fails for the same reason that Petitioner's "fundamental fairness" argument fails.

Petitioner argues that "[f]undamental fairness and due process requires [sic] the revocation be set aside." P. Br. at 22. My authority is limited to determining whether there is a basis for revocation of Petitioner's Medicare enrollment and billing privileges. I have no authority to review the exercise of discretion by CMS to revoke where there is a basis for revocation. *Abdul Razzaque Ahmed, M.D.*, DAB No. 2261, at 19 (2009). To the extent Petitioner's arguments are construed as a request for equitable relief, I have no authority to grant equitable relief. *US Ultrasound*, DAB No. 2302, at 8 (2010) ("[n]either the ALJ nor the Board is authorized to provide equitable relief by reimbursing or enrolling a supplier who does not meet statutory or regulatory requirements."). I am also required to follow the Act and regulations and have no authority to declare statutes or

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[5] Petitioner states that the entity PremierTox 2.0 "entered into a Corporate Integrity Agreement with CMS and HHS." This is a mischaracterization of the parties to the CIA. PremierTox 2.0 entered into the agreement with the IG, not CMS. P. Ex. 1. CMS and the IG are both part of HHS, and, for most purposes, subject to control of the Secretary of HHS. However, Congress and the Secretary have imposed a division of labor and delegation of different authorities to CMS and the IG. Generally, CMS would arguably be bound by the terms of the CIA, but that is not the issue before me.

regulations invalid. *1866ICPayday.com, L.L.C.*, DAB No. 2289, at 14 ("[a]n ALJ is bound by applicable laws and regulations and may not invalidate either a law or regulation on any ground.").

Petitioner does not deny the material facts and any favorable inferences are drawn for Petitioner in this decision. Applying the law to the undisputed facts, I conclude that there was a basis for revocation of Petitioner's billing privileges and enrollment pursuant to 42 C.F.R. § 424.535(a)(1), effective November 14, 2013.

CMS argues two additional bases for revocation in its briefs: that Petitioner abused its billing privileges under 42 C.F.R. § 424.535(a)(8), and that Petitioner was not operational under 42 C.F.R. § 424.535(a)(5). CMS Br. at 1-2, 8 n.5. It is not necessary for me to consider these additional alleged bases for revocation because I conclude that there is a basis for revocation of Petitioner's Medicare enrollment and billing privileges pursuant to 42 C.F.R. § 424.535(a)(1). CMS only needs a single basis under 42 C.F.R. § 424.535(a) to revoke Medicare billing privileges and enrollment. Furthermore, the evidence before me on these alternate grounds is insufficient for summary judgment and a hearing on the merits would be required prior to a determination on either alternate ground.

III. Conclusion

For the foregoing reasons, I conclude that Petitioner's Medicare enrollment and billing privileges are properly revoked effective November 14, 2013.

/s/
Keith W. Sickendick
Administrative Law Judge