Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Nexus Lab Inc.,[1]
(NPI: 1447581558; PTAN: 01467),
and
Nexus Lab 2.0, LLC, Inc.
(NPI: 1679861678; PTANs: K044771, K044772),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-14-787

Decision No. CR3382

Date: September 23, 2014

DECISION

The Medicare enrollment and billing privileges of Petitioners, Nexus Lab Inc. (Nexus) and Nexus Lab 2.0, LLC , Inc. (Nexus 2.0), are revoked pursuant to 42 C.F.R. § 424.535(a)(1),[2] effective October 24, 2013.

---

[1] This case was docketed as Nexus Lab, Inc. The request for hearing, however, states that Nexus Lab, Inc. was merged into Nexus Lab 2.0, LLC, and Nexus Lab 2.0, LLC is the correct name for the surviving entity that filed the request for hearing. The assertion is consistent with the CMS evidence. CMS Ex. 4 at 5. I treat the request for hearing to cover both entities as CMS and its contractor took action against both and the request for hearing was timely as to both.

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

I. Background

CGS Administrators, LLC (CGS), the Centers for Medicare & Medicaid Services (CMS) Medicare contractor, notified Petitioner Nexus 2.0 by letter dated September 24, 2013, that its Medicare billing number and billing privileges were revoked effective October 24, 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 pursuant to 42 C.F.R. § 424.535(c). CMS Ex. 1 at 8-9. On November 22, 2013, Petitioner Nexus 2.0 submitted a request for reconsideration that Petitioner supplemented on January 17, 22, and 27, 2014. CMS Ex. 1 at 11-196. 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.

On October 15, 2013, CGS sent a notice of initial determination to Petitioner Nexus, advising that its Medicare billing privileges and enrollment were revoked effective September 10, 2013. CMS Ex. 1 at 271-72. The bases cited were 42 C.F.R. §§ 424.535(a)(1) and (5). Petitioner Nexus requested reconsideration on December 12, 2013. CMS Ex. 1 at 270, 273-416. On February 11, 2014, the reconsidered determination upheld revocation based on violations of 42 C.F.R. §§ 424.535(a)(1) and (5)(ii). CMS Ex. 1 at 262-66.

Petitioners 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 4. On May 26, 2014, Petitioner filed its opposition to CMS's motion for summary judgment (P. Br.), accompanied by an unmarked exhibit, 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. Petitioner failed to mark this 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). Because there is little risk for confusion when referring to Petitioner's exhibits, Petitioner was not required to file a corrected exhibit and Petitioner's exhibit is referred to as it is listed in DAB e-File. On June 10, 2014, CMS filed a reply (CMS 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 16, 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 it were marked P. Ex. 2. The parties' supplemental briefings are accepted.

In the CMS Reply, CMS objected to the admission of the CIA (P. Ex. 1) on the grounds that the document was not relevant. CMS Reply at 3 n.1. The CMS objection is sustained. Petitioner has not shown that the CIA is relevant to any issue that I may decide. No objections have been made to the other offered exhibits and CMS Exs. 1 through 4 and P. Ex. 2 are admitted as evidence. P. Ex. 1 remains part of the record though it is not admitted and considered as substantive 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.[3] 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

---

[3] 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.

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 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 (Fed. R. Civ. Pro.) do not apply in administrative adjudications such as this, but the Board has accepted that Fed. R. Civ. Pro. 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 & 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.

The notices of the initial and reconsidered determinations advised Petitioner Nexus 2.0 that its enrollment and billing privileges were also revoked pursuant to 42 C.F.R.

§ 424.535(a)(8). Petitioner Nexus was advised that its enrollment and billing privileges were also revoked pursuant to 42 C.F.R. § 424.535(a)(5). Summary judgment is not appropriate for revocation pursuant to 42 C.F.R. §§ 424.535(a)(5) or (8), because the alternative bases involve genuine disputes as to material fact that would require a trial. If CMS desires a hearing to attempt to prove that revocation should be effective September 10, 2013, based on revocation pursuant to 42 C.F.R. § 424.535(a)(5), CMS will file an appropriate motion to reopen and revise pursuant to 42 C.F.R. § 498.100-.103, so that the record may be reopened and a hearing convened to receive evidence on that issue.

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

3. Petitioners' enrollment in Medicare and its billing privileges are revoked effective October 24, 2013.

a. Facts

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

Petitioners operated clinical laboratories in Kentucky.[4] Petitioner Nexus submitted a Medicare enrollment application (Form CMS-855B) to the Medicare contractor, CGS, dated January 31, 2011. CMS Ex. 2 at 38-51. The application's "Certification Statement" was signed by Robert L. Bertram, Petitioner's President, on January 31, 2011. CMS Ex. 2 at 49-51. 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 50. Petitioner was assigned National Provider Identifier (NPI) 11447581558. CMS Ex. 2 at 44. Petitioners acknowledge they are ultimately responsible for claims submitted on their behalf. CMS Ex. 1 at 12; P. Br. at 6,

Petitioner Nexus 2.0 submitted a Medicare enrollment application (Form CMS-855B) to the Medicare contractor, CGS, dated January 3 and February 17, 2012. CMS Ex. 2 at 1-37. The application's "Certification Statement" was signed by Eric Duncan,

---

[4] Nexus Lab 2.0, LLC, was organized as a Kentucky limited liability corporation in July 2011, by W. Bradford Boone. Robin Peavler was listed as a member in the corporate papers. CMS Ex. 4 at 2. Nexus Lab, Inc. was organized as a Kentucky corporation in January 2010, by Robert L. Bertram, Jr. Robert L. Bertram, Jr. was the President, Robert L. Bertram, Sr. was the Vice President, Bryan Wood was the Secretary, and Robin Peavler was the Treasurer. CMS Ex. 4, at 5.

Chief Executive Officer. CMS Ex. 2 at 30-31. Petitioner indicated in the application that it would be submitting its claims for Medicare payment through a billing agency, Liberty Billing, 2.0, LLC (Liberty). 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 25. 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 29. The application reflects Petitioner Nexus 2.0's NPI 1679861678. CMS Ex. 1 at 5; 2 at 3.

CGS notified Petitioner Nexus on October 15, 2013, that from November 1, 2010 through July 1, 2012, 1920 Medicare claims for clinical laboratory services provided by Petitioner Nexus for Medicare-eligible beneficiaries were submitted by Liberty without the NPI of the physician who ordered the services. It is alleged that the claims were submitted with Petitioner's own NPI listed as both the "rendering" and the "referring" NPI. CMS Ex. 1 at 268, 271. CMS submitted a list of 1885 individual claims from February 1, 2011 through December 29, 2011, that list Petitioner Nexus's NPI 1447581558 as both the rendering and the referring NPI. I note that the list reflects multiple claims for individual beneficiaries. CMS Ex. 1 at 434-68. Petitioner does not dispute that claims were submitted on which its NPI was listed as both the rendering and referring NPI.

CGS notified Petitioner Nexus 2.0 on September 24, 2013, that from July 1, 2012 through July 1, 2013, 1343 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. It is alleged that the claims were submitted with Petitioner's own NPI listed as both the "rendering" and the "referring" NPI. CMS Ex. 1 at 6, 8. CMS submitted a list of 2972 individual claims from January 2012 through July 2013, that lists Petitioner's NPI 1679861678 as both the rendering and the referring NPI. I note that the list reflects multiple claims for individual beneficiaries. CMS Ex. 1 at 201-59. Petitioner Nexus 2.0 has not disputed that claims were submitted on which its NPI was listed as both the rendering and the referring NPI.

Petitioners admit that Liberty submitted claims on their behalf to Medicare for payment that omitted the NPI for the physician or other authorized individual who ordered laboratory services. Petitioners allege that they had no knowledge of the errors of Liberty until they were notified of the revocation of their billing privileges and Medicare enrollment. RFH at 6-7; P. Br. at 3-7, 8-9; P. Supp. Br. at 1. Petitioners submitted a Corrective Action Plan that was not accepted by CMS. RFH at 5, 7; P. Br. at 4, 9, 14-15, 20-22; CMS Br. at 8 n.6.

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). Petitioners were entitled to receive payment for clinical laboratory services 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, Petitioners 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 clinical laboratories, Petitioners were 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 Petitioners' Medicare enrollment applications (Form CMS-855B) clearly informed Petitioners that, if they used a billing agency, they were responsible for claims submitted on their behalf. Petitioners also agreed in the application to abide by Medicare laws, regulations, and program instructions. Petitioners also acknowledged in the application that the payment of a claim was conditioned upon the underlying transaction being compliant with Medicare law and regulations.

It is undisputed that Liberty submitted claims to Medicare on Petitioners' 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 Petitioners agreed to comply upon enrollment.

Section 424.535(a)(1) of Title 42 C.F.R. requires that Petitioners 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 notices of initial determination

advised Petitioners of the right to submit a CAP and to request reconsideration. Petitioners submitted a CAP and request for reconsideration. The revocations were upheld on reconsideration and the CAP was apparently found not acceptable inasmuch as CMS persists with the revocation action before me.

Petitioners argue that the failure of CGS and CMS to accept Petitioners' CAP was in error. RFH at 5, 7. However, the refusal of CMS or its contractor to accept Petitioners' 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). Petitioners cite no authority to the contrary.

Petitioners argue that the billing errors involved were solely the fault of Liberty, and should not be attributed to Petitioners, who were unaware of the company's misconduct. P. Br. at 3-10. Petitioners contend 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 24. I accept as true for purposes of summary judgment that Petitioners had no actual knowledge of Liberty's erroneous listing of Petitioners' NPI as the referring NPI. However, Petitioners are nevertheless ultimately responsible, both as a matter of law and under the terms of their participation agreements, for ensuring that their 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). Petitioners cannot avoid responsibility for their 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 Petitioners' assertions that there was no evidence of fraud. P. Br. at 7. But Petitioners cite no authority for the proposition that the absence of fraud or fraudulent intent relieves Petitioners of their responsibility for their Medicare claims. Petitioners also argue that they were in substantial compliance citing 42 C.F.R. § 488.301. P. Br. at 12. Petitioners have 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. Petitioners are clinical laboratories not long-term care facilities. 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.

Petitioners argue that "[f]undamental fairness and due process requires [sic] the revocation be set aside." P. Br. at 22. Further, Petitioners argue that they should be treated the same as PremierTox 2.0, which was permitted to enter a CIA with the Inspector General (IG) for the Department of Health and Human Services (HHS) and continues to operate as a laboratory. P. Supp. Br. My authority is limited to determining whether there is a basis for revocation of Petitioners' 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 Petitioners' 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 regulations invalid. *1866ICPayday.com, L.L.C.*, DAB No. 2289, at 14 (2009) ("[a]n ALJ is bound by applicable laws and regulations and may not invalidate either a law or regulation on any ground.").

Petitioners do not deny the material facts and any favorable inferences are drawn for Petitioners in this decision. Applying the law to the undisputed facts, I conclude that there was a basis for revocation of Petitioners' billing privileges and enrollment pursuant to 42 C.F.R. § 424.535(a)(1), effective October 24, 2013.

CMS argues additional bases for revocation under 42 C.F.R. §§ 424.535(a)(5) and (8). But, it is not necessary for me to consider the additional alleged bases for revocation because I conclude that there is a basis for revocation of Petitioners' 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 the alternate grounds is insufficient for summary judgment and a hearing on the merits would be required prior to a determination on the alternate grounds.

III. Conclusion

For the foregoing reasons, I conclude that Petitioners' Medicare enrollment and billing privileges are properly revoked effective October 24, 2013.

/s/
Keith W. Sickendick
Administrative Law Judge