

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Recovery Laboratory, LLC,  
(NPI: 1003166224; PTAN: K089620),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-14-794

Decision No. CR3381

Date: September 23, 2014

**DECISION**

The Medicare enrollment and billing privileges of Petitioner, Recovery Laboratory, LLC, are revoked pursuant to 42 C.F.R. § 424.535(a)(1),<sup>1</sup> effective October 24, 2013.

**I. Background**

CGS Administrators, LLC (CGS), the Centers for Medicare & Medicaid Services (CMS) Medicare contractor, notified Petitioner 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) as the basis for revocation. CMS Exhibit (CMS Ex.) 1 at 4-5, 25-26. 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 5, 26.

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<sup>1</sup> Citations to the 2013 revision of the Code of Federal Regulations (C.F.R.), unless otherwise stated.

On November 22, 2013, Petitioner submitted a request for reconsideration. CMS Ex. 1 at 11-62. On February 11, 2014, a contractor hearing officer issued a reconsidered determination in which she upheld the revocation pursuant to 42 C.F.R. § 424.535(a)(1). CMS Ex. 1 at 7-10.

Petitioner filed a request for hearing (RFH) before an administrative law judge (ALJ) on March 16, 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 to dismiss, or in the alternative, for summary judgment (CMS Br.), with CMS Exs. 1 through 5. On May 27, 2014, Petitioner filed its opposition to CMS's motions (P. Br.). On June 10, 2014, CMS filed a reply. Petitioner did not object to CMS Exs. 1 through 5 and they 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.<sup>2</sup> 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

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<sup>2</sup> 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.

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 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 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.

CMS filed a motion to dismiss or in the alternative for summary judgment. The CMS motion to dismiss is denied. The CMS theory for dismissal is that Petitioner conceded in its request for hearing that it ceased operations months before it was notified of the revocation. RFH at 8. CMS contends that Petitioner's enrollment could also be revoked pursuant to 42 C.F.R. § 424.535(a)(5) because Petitioner is no longer operational. CMS also argues that Petitioner's request for hearing is "moot" but CMS fails to explain why Petitioner would not have a right to review of a revocation based on 42 C.F.R. § 424.535(a)(5). CMS Br. at 2-3. Petitioner disputes CMS's claim that it was not operational when it received the revocation notice, stating that it "was a current services provider for Medicare" at the time the revocation was issued. P. Br. at 1. CGS did not cite 42 C.F.R. § 424.535(a)(5) as a ground for revocation in either the initial determination or the reconsidered determination. CMS has not requested remand to consider and develop a proper record related to the alternative basis. The Departmental Appeals Board (Board) has concluded in prior cases that only the regulatory basis for CMS action articulated in the initial and reconsidered determinations are properly before an ALJ and the Board for review. *Neb Group of Arizona LLC*, DAB No. 2573, at 7 (2014); *Benson Ejindu, d/b/a Joy Medical Supply*, DAB No. 2572, at 8-9 (2014). I also conclude that the only basis for revocation properly before me is 42 C.F.R. § 424.535(a)(1). CMS's motion to dismiss is denied, and I decide this case on CMS's summary judgment motion. If counsel for CMS had authority to add a basis for revocation at this stage without according Petitioner the process required by the regulations; summary judgment would not be appropriate related to 42 C.F.R. § 424.535(a)(5) as I would conclude that there are genuine disputes of material fact related to that basis.

### **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.<sup>3</sup> 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.

**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 October 24, 2013.**

**a. Facts**

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

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<sup>3</sup> In its brief, CMS erroneously states that Petitioner's Medicare enrollment and billing privileges were also revoked pursuant to 42 C.F.R. § 424.535(a)(8), based on Petitioner's abuse of billing privileges. CMS Br. at 1. The only basis for revocation cited by the Medicare contractor in the initial notice of revocation and the reconsideration decision is 42 C.F.R. § 424.535(a)(1). CMS Ex. 1, at 4-5, 7-10, 25-26.

Petitioner operates a clinical laboratory in Kentucky.<sup>4</sup> CMS Ex. 2 at 4. Petitioner submitted a Medicare enrollment application (Form CMS-855B) to the Medicare contractor, CGS, signed and dated by Jamie Durham, Chief Financial Officer, on December 29, 2012. CMS Ex. 2 at 27. Petitioner indicated in the application that it would be submitting claims for Medicare payment through a billing agency, Liberty Billing 2.0, LLC (Liberty).<sup>5</sup> CMS Ex. 2 at 20. The following NPI was assigned to Petitioner: 1003166224. CMS Ex. 2 at 32.

CMS and CGS alleged that between July 1, 2012 and July 1, 2013, 42 unique 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 3, 4, 25. CMS submitted a list of 38 claims from January 11, 2013 through August 2, 2013, that list Petitioner's NPI 1003166224 as both the rendering and referring NPI. I note that the list reflects multiple claims for individual beneficiaries. CMS Ex. 1 at 64-66.

Petitioner does not dispute that Medicare claims were filed by Liberty on Petitioner's behalf without the referring physician or eligible professional's NPI and with Petitioner's NPI listed as both the rendering and referring NPI. It is not necessary to resolve the exact number of such claims that were filed by Liberty with this error. Petitioner alleges no knowledge of the errors of Liberty until it was notified of the revocation of its billing privileges and Medicare enrollment. RFH at 1, 4-6; P. Br. at 2-5, 7, 9-10; CMS Ex. 1 at 12-13, 15-16, 18. Petitioner submitted a Corrective Action Plan (CAP) that was not accepted by CMS. RFH at 4, 6; P. Br. at 1, 11, 14; CMS Ex. 1 at 19-20, 22-24; CMS Br. at 8 n.3.

### **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:

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<sup>4</sup> Petitioner is a Kentucky limited liability company (LLC) formed in September 2012, by James Durham. CMS Ex. 4. Petitioner's application to enroll in Medicare lists as owners: Jonathan Meyer, Robert Durham, J. Todd Clark, and Jamie Durham. CMS Ex. 2 at 12-15.

<sup>5</sup> Liberty is a Kentucky LLC organized in August 2011. Members of Liberty were Bryan Wood, Robin Peavler, Brian Walters, James Bottom, and Robert Bertram. CMS Ex. 3 at 1, 5.

(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 20. Petitioner agreed in the application to abide by Medicare laws, regulations, and program instructions. CMS Ex. 2, at 24-27. 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 25.

It is undisputed that Liberty 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 September 24, 2013 notice of initial determination advised Petitioner of the right to submit a CAP and to request reconsideration. CMS Ex. 1 at 4-5, 25-26. Petitioner submitted a CAP and request for reconsideration. CMS Ex. 1 at 11-24, 27-59. 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 7-10; CMS Br. at 8 n.3.

Petitioner argues that the failure of CGS and CMS to accept Petitioner's CAP was in error. RFH at 4, 6; P. Br. at 1, 11, 14. 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 2-5, 7, 9-10. Petitioner contends that issues of material fact exist. P. Br. at 15-17. 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 concedes that it is ultimately responsible for its claims. CMS Ex. 1 at 12. 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. P. Br. at 5-7; CMS Ex. 1 at 12. 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 contends further that "[f]undamental fairness and due process requires the revocation be set aside." P. Br. at 17. 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 that Petitioner is seeking 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.").

