Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

D & G Holdings, LLC d/b/a Doctors Lab,
(NPI: 1376760728),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-13-1336

Decision No. CR3120

Date: February 12, 2014

DECISION

There is no basis for the revocation of the Medicare enrollment and billing privileges of Petitioner, D & G Holdings, LLC d/b/a Doctors Lab.

I. Procedural Background

Novitas Solutions, Inc. (Novitas), the Centers for Medicare & Medicaid Services (CMS) Medicare contractor, notified Petitioner by letter dated May 30, 2013, that its Medicare billing privileges were to be revoked effective June 29, 2013. Novitas cited 42 C.F.R. § 424.535(a)(8) [1] as the basis for revocation. Novitas advised Petitioner that Petitioner was barred from re-enrolling for two years. CMS Exhibit (CMS Ex.) 6; Petitioner's Exhibit (P. Ex.) 6. Petitioner requested reconsideration by a contractor hearing officer who issued a reconsideration determination on August 13, 2013. The hearing officer concluded that there was a basis for revocation, also citing 42 C.F.R. § 424.535(a)(8).

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[1] Citations to the Code of Federal Regulations (C.F.R.) are to the version in effect at the time of the revocation, unless otherwise stated.

CMS Ex. 1; P. Ex. 10. Petitioner requested a hearing before an administrative law judge (ALJ) by letter dated September 13, 2013, requesting an expedited decision. On September 19, 2013, the case was assigned to me for hearing and decision and an Acknowledgment and Prehearing Order (Prehearing Order) was issued at my direction.

On October 28, 2013, Petitioner filed its prehearing exchange and a motion for summary judgment (P. MSJ.) with P. Exs. 1 through 21. CMS filed a motion to dismiss (CMS MTD), also on October 28, 2013, with CMS Exs. 1 and 2. On November 5, 2013, CMS filed a motion for summary judgment (CMS MSJ)[2] with CMS Exs. 3 through 7. Petitioner filed an opposition to the CMS motion to dismiss on November 13, 2013 (P. Opp. MTD). Petitioner also filed its opposition to the CMS motion for summary judgment on November 13, 2013 (P. Opp. MSJ), with P. Exs. 22 through 31. On December 20, 2013, CMS filed a "Reply to Petitioner's Fact Contentions, Arguments and Submissions of New Evidence," (CMS Reply) with CMS Ex. 8. On January 7, 2014, Petitioner filed a "Reply to CMS's Opposition to Petitioner's Motion for Summary Judgment" (P. Reply). Petitioner requested the issuance of subpoenas on February 4, 2014; however, subpoenas will not be necessary in light of my decision.

CMS does not object to P. Exs. 1 through 10. CMS objects to P. Exs. 11 through 31, citing 42 C.F.R. § 498.56 and arguing that those exhibits are new evidence not offered at reconsideration and there is no good cause for me to admit and consider the exhibits. CMS Reply at 2-6. Pursuant to 42 C.F.R. § 405.803(a), the procedures applicable in this case are those established by 42 C.F.R. pt. 498. The following rule applies in provider and supplier-related cases:

> (e) *Provider and supplier enrollment appeals: Good cause requirement—*
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> (1) *Examination of any new documentary evidence*. After a hearing is requested but before it is held, the ALJ will examine any new documentary evidence submitted to the ALJ by a provider or supplier to determine whether the provider or supplier has good cause for submitting the evidence for the first time at the ALJ level.
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> (2) *Determining if good cause exists—*

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[2] Because parts of the CMS motion for summary judgment were unreadable or missing, CMS filed a corrected copy on December 30, 2013, at my direction.

> (i) *If good cause exists.* If the ALJ finds that there is good cause for submitting new documentary evidence for the first time at the ALJ level, the ALJ must include evidence and may consider it in reaching a decision.
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> (ii) *If good cause does not exist.* If the ALJ determines that there was not good cause for submitting the evidence for the first time at the ALJ level, the ALJ must exclude the evidence from the proceeding and may not consider it in reaching a decision.
>
> (2) *Notification to all parties*. As soon as possible, but no later than the start of the hearing, the ALJ must notify all parties of any evidence that is excluded from the hearing.

42 C.F.R. § 498.56(e) (emphasis and incorrect numbering of subsections as in original). The regulation is clear on its face that it applies only to documentary evidence and that "new documentary evidence" is evidence offered for the first time at the ALJ-level. No definition of good cause was established by CMS when it promulgated this regulation on behalf of the Secretary.[3] The regulation requires that the ALJ examine any new documentary evidence to determine if good cause exists for submission of the evidence for the first time at the ALJ-level. I am bound to follow the Secretary's regulations and apply them harmoniously and consistently with the Constitution, the Social Security Act (the Act), and the Secretary's other regulations.

I consider first the adequacy of the notice that Petitioner received in determining if it may be barred from presenting evidence for the first time before me. Petitioner should not be deprived of an opportunity to submit evidence for consideration if it was not informed when to submit evidence in support of its request for reconsideration or be barred from doing so subsequently. The May 30, 2013 notice of revocation advised Petitioner that it could request reconsideration before a contractor hearing officer; that reconsideration is an independent review by one not involved in the initial determination; that

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[3] The definition of "good cause" as the phrase has been used in various contexts in 42 C.F.R. pt. 498 is a long-standing issue that CMS has apparently chosen not to resolve by promulgating a regulation that gives clarity and certainty. CMS is correct that there are prior decisions of the Board and ALJs construing good cause to be some cause not within the control of the party seeking to establish good cause. "Good cause" as defined in *Black's Law Dictionary* 235 (8th ed. 2004) is "[a] legally sufficient reason." I do not decide which definition is more correct but consider both when concluding that good cause exists in this case.

reconsideration had to be requested within 60 calendar days of the postmark on the initial determination; that Petitioner must state the issues and facts with which it disagreed and the reason for the disagreement; and that Petitioner "may" submit additional information that may have a bearing. CMS Ex. 6 at 1; P. Ex. 6 at 1. There is no description of the procedures that would be followed on reconsideration; whether the additional information had to be submitted with the request for reconsideration; or a warning that failure to submit more information at a specific time in the reconsideration stage could serve to bar submission of the evidence to the ALJ. The regulations that control reconsideration do not specify when evidence must be submitted to the hearing officer on reconsideration. The regulations provide that when a request for reconsideration is properly filed, then CMS receives written evidence and statements relevant to the matters at issue and submitted within a reasonable time after the request for reconsideration is filed. 42 C.F.R. §§ 498.22 and 498.24(a). Further, 42 C.F.R. § 405.803(d) provides that "[i]f supporting evidence is not submitted with the appeal request, the contractor contacts the provider or supplier to try to obtain the evidence." The reconsideration request was received by Novitas on July 16, 2013, and the reconsideration decision was issued on August 13, 2013, less than 30 days later. The reconsideration decision does not reflect that Petitioner was advised of a date by which additional evidence had to be submitted or that failure to timely submit evidence during the reconsideration process might bar future consideration of such evidence. The reconsideration hearing officer also failed to comply with 42 C.F.R. § 405.803(d), for despite the fact that Petitioner's request for reconsideration clearly stated that there was other evidence that Petitioner was collecting (CMS Ex. 7; P. Ex. 8), the reconsideration hearing officer did not request or establish a time for the submission of that evidence by Petitioner prior to issuance of the reconsideration determination. The failure to comply with the regulations and the failure to give Petitioner notice of when evidence had to be submitted on reconsideration are both a legally sufficient basis and beyond Petitioner's control. Accordingly, good cause exists for the submission of new documentary evidence to me.

Petitioner argues that there is good cause to admit new documentary evidence marked as P. Exs. 11, 12, 15, 16, 17, and 18, because those documents were not released to Petitioner by CMS until after the reconsideration decision was issued. P. MSJ at 15-17. CMS argues that any delay in Petitioner receiving the documents was Petitioner's fault, not that of CMS or its contractor, and Petitioner should have had copies of the requested documents in its files. CMS Reply at 2-5. Petitioner responds that the documents it requested that were not produced by CMS until after the reconsideration decision were the documents upon which the allegations of abuse of billing privileges were based. P. Reply at 1-2. The CMS argument is without merit. CMS may not proceed based on mere allegations but at some point must produce the evidence it relies upon in support of its allegations. Petitioner made clear in its request for reconsideration dated July 15,

2013, that it wished to examine the documents underlying the CMS allegation that claims for 26 beneficiaries constituted an abuse of billing privileges.[4] CMS Ex. 7. The request to examine the documents was not acted upon by CMS or its contractor Novitas before the reconsideration decision was issued on August 13, 2013, which summarily upheld the revocation. Although the reconsideration decision states that evidence in the file was considered, the contents of the file are not enumerated in the decision. In fact, the documents Petitioner sought should have been in the file to which the reconsideration decision referred and, therefore, would not be considered new evidence at all. Even if one concluded that it is permissible for CMS or its contractor to withhold disclosure of the evidence supporting the initial determination and to not make that evidence available at reconsideration, Petitioner is entitled to a de novo review before an ALJ. The failure of CMS to produce the evidence that is the basis for its adverse determinations may cause the conclusion that CMS has failed to make a prima facie showing of the basis for its adverse initial and reconsideration determinations. The failure of CMS and Novitas to grant Petitioner access to the evidence underlying the CMS initial determination is cause beyond the control of Petitioner and provides a further legally sufficient basis to permit the introduction of the evidence for the first time before me.

CMS objects to my consideration of P. Ex. 15, the declaration of Donna Poimboeuf, Petitioner's owner and operator. The CMS objection is that the declaration of Donna Poimboeuf does not state specifically that it was based on personal knowledge, that she prepared, observed, or otherwise was involved in the preparation of any billing statements, and does not establish in any other way that she has personal knowledge regarding the preparation of billing statements. CMS argues that Petitioner has failed to show that Ms. Poimboeuf is competent to testify regarding any claims involved. CMS Reply at 15-16. CMS apparently overlooked the first sentence of the declaration which specifically states that it is based on personal knowledge. The declaration was also affirmed subject to the penalty for perjury. P. Ex. 15 at 1. CMS also does not question the authenticity of the declaration or that it is relevant and, accordingly, the declaration is

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[4] As early as March 8, 2013, Petitioner sought to obtain documents that related to the allegations of abuse of billing privileges through the Freedom of Information Act (FOIA). P. Ex. 3. Novitas denied the FOIA request on grounds that there were no individual authorizations for release of health care information as required by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), even though the basis for the alleged abuse of billing privileges was that all the beneficiaries were dead, and arguably, could not execute such releases if HIPAA even applied under the circumstances. P. Ex. 4. Petitioner filed a second FOIA request on June 12, 2013, but limited that request to the 26 deceased beneficiary claims at issue according to the notice of revocation dated May 30, 2013. P. Ex. 7. CMS released documents to Petitioner on August 16, 2013.

admissible in this administrative proceeding. The CMS argument goes to the weight of the testimony contained in the declaration. Accordingly, the CMS objection is overruled. I further note that contrary to the argument of CMS, the declaration reflects on its face that Ms. Poimboeuf is the owner and operator of Petitioner. Pursuant to the regulations, a laboratory's owner and operator is responsible for the operations of the laboratory including the policies, procedures, and practices of the laboratory specified by 42 C.F.R. pt. 493. 42 C.F.R. § 493.1840. Indeed, the owner and operator responsibilities under the regulation are so extensive as to trigger a rebuttable presumption that the owner and operator has knowledge of the workings and activities of the laboratory.

CMS objects to my consideration of P. Ex. 16, the declaration of Tracie Underwood, an employee of the billing company that handled Petitioner's billing. CMS objects that Ms. Underwood's declaration does not demonstrate that she has personal knowledge of the claims at issue. CMS Reply at 17. Contrary to the CMS argument, Ms. Underwood declared and affirmed that she had personal knowledge of the contents of her declaration in the first sentence. She also executed her affidavit with knowledge that she could be subjected to a penalty for perjury. CMS does not object to the authenticity of the declaration or claim that the matters asserted are not relevant. Ms. Underwood's affidavit is admissible. Furthermore, the declaration is appropriate for consideration on summary judgment or on the merits. Ms. Underwood clearly states the basis for her personal knowledge and clearly identifies the limits of her recollection regarding specific claims forms.

CMS also argues that P. Exs. 22 through 31 are not related to any claim before me and are therefore not relevant. CMS Reply at 6. P. Exs. 22 through 31 are related to the beneficiaries, Mary C., Dorothy L., Robert G., and James W, all of whom are currently deceased. CMS Exs. 3 and 4 reflect that Petitioner explained the errors in the claims related to the aforementioned four beneficiaries to the satisfaction of Novitas. Petitioner does not dispute that claims related to these four beneficiaries are not at issue before me. Petitioner argues that the documents marked P. Exs. 22 through 31 are relevant, however, because they show that the information on which the CMS allegations were based is simply unreliable and incorrect. P. Reply at 3; P. MSJ at 29-35. I agree with Petitioner that P. Exs. 22 through 31 are relevant in support of Petitioner's defense theory.

Accordingly, CMS Exs. 1 through 8 and P. Exs. 1 through 31 are admitted and considered as evidence.

II. Discussion

A. Statutory and Regulatory Program Requirements

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. Administration of the Part B program is through contractors such as Novitas. 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.[5] Act §§ 1835(a) (42 U.S.C. § 1395n(a)); 1842(h)(1) (42 U.S.C. § 1395(u)(h)(1)). Petitioner 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, including 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 to be reimbursed for services provided to Medicare beneficiaries. Participation in Medicare imposes obligations upon a supplier. 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 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 supplier is aware of and agrees to abide 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, .516, .517. Suppliers are also subject to additional screening requirements depending upon the type of service they provide. 42 C.F.R. § 424.518.

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[5] 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) and 1835(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.

Once enrolled, the supplier receives billing privileges and is issued a billing number that is required to receive payment for services rendered to a Medicare beneficiary. 42 C.F.R. § 424.505. The supplier is subject to a five-year revalidation of enrollment cycle and CMS is authorized to perform off cycle revalidations for a number of reasons. CMS has the right to perform on-site inspections to verify that the information CMS receives is correct. CMS contacts the supplier directly when it is time to revalidate enrollment information. A supplier must submit the applicable enrollment information, with complete and accurate information and supporting documentation, within 60 calendar days of CMS's notification. 42 C.F.R. § 424.515. There is no issue in this case that Petitioner was enrolled in Medicare as a supplier of clinical laboratory services.

Many clinical laboratory services are covered by Medicare, when properly ordered by a physician or other qualified individual. 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). There is no issue in this case that Petitioner was an authorized provider of clinical laboratory services with a Clinical Laboratory Improvement Amendments (CLIA) certificate issued in accordance with 42 C.F.R. pt. 493.

CMS or its Medicare contractor has been delegated authority to revoke an enrolled provider or supplier's Medicare enrollment and billing privileges and any provider or supplier agreement for any of the reasons listed in 42 C.F.R. § 424.535(a). In this case Petitioner was notified that its enrollment and billing privileges were being revoked pursuant to 42 C.F.R. § 424.535(a)(8), which authorizes revocation if a provider or supplier "submits a claim or claims for services that could not have been furnished to a specific individual on the date of service." The regulation provides examples to clarify its application as follows: "[t]hese instances include but are not limited to situations where the beneficiary is deceased, the directing physician or beneficiary is not in the State or country when services were furnished, or when the equipment necessary for testing is not present where the testing is said to have occurred." 42 C.F.R. § 424.535(a)(8).

A supplier who has been denied enrollment or whose enrollment and billing privileges have been revoked has a right to request a hearing by an ALJ and further review by the Departmental Appeals Board (the Board). 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).

B. Issue

Whether there was a basis for 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. The findings of fact are based upon the exhibits admitted. 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.[6] 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).

1. Judgment on the written pleadings and documentary evidence is permissible in this case.

The parties have filed cross-motions for summary judgment in this case. Summary judgment is not automatic upon request but is limited to certain specific conditions. The procedures established by 42 C.F.R. pt. 498 related to ALJ hearings applicable in this case do not include a summary judgment procedure. However, the Board has long recognized the availability of summary judgment in cases subject to 42 C.F.R. pt. 498 and the Board's interpretative rule has been recognized by the federal courts. *See e.g. Crestview*, 373 F.3d at 749-50. 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. Prehearing Order §§ II.D and II.G. The Board has explained, consistent with its prior decisions, that the ALJ's role in deciding summary judgment is different from deciding a case on the merits after a hearing. On summary judgment, credibility determinations are not made, the evidence is not weighed, and the ALJ does not decide which inferences to draw from the facts. Rather, the evidence of record is construed in a light most favorable to the nonmovant without determining which version of the facts is more likely true. *Ill. Knights Templar Home*, DAB No. 2274, at 8 (2009).

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[6] "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.

Pursuant to 42 C.F.R. § 498.66(a), an affected party, such as Petitioner, may waive its right to appear and present evidence at an oral hearing by filing a written waiver. When a written waiver is filed by a petitioner, an ALJ need not conduct an oral hearing except in two circumstances: the ALJ concludes witness testimony is necessary to clarify facts at issue; or CMS shows good cause for presenting oral testimony. 42 C.F.R. § 498.66(b). Petitioner states in the conclusion of its motion for summary judgment that it is in Petitioner's best interest to waive its right to a hearing to avoid the delay associated with a hearing and Petitioner rests with its motion for summary judgment and exhibits.[7] P. MSJ at 35-36. I construe Petitioner's statement to be a written waiver of the right to oral hearing consistent with the requirements of 42 C.F.R. § 498.66(a). After review of the evidence and pleadings of the parties, I conclude that oral testimony is not necessary for clarification of the facts at issue. CMS has not argued that oral testimony is necessary or otherwise shown good cause to convene an oral hearing.

In accordance with 42 C.F.R. § 498.66, the record of the hearing in this case without oral testimony consists of the documentary evidence admitted and the parties' pleadings. The parties exchanged the evidence before me by use of the Departmental Appeals Board electronic filing system (DAB e-File). The parties also had a reasonable opportunity for rebuttal as reflected by their various filings.

Accordingly, this decision is on the merits and not based on summary judgment.

2. The evidence does not establish an abuse of billing privileges within the meaning of 42 C.F.R. § 424.535(a)(8).

3. CMS has failed to make a prima facie showing of a basis for the revocation of Petitioner's billing privileges and Medicare enrollment.

An unusual aspect of this case is that the parties are not in agreement as to what is at issue. Specifically, the parties do not agree as to which alleged claims were the bases for the Novitas initial determination that Petitioner abused its billing privileges. Only the

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[7] It is possible to interpret Petitioner's conclusion as waiving an oral argument on the motion for summary judgment. However, there is no regulatory or statutory right to present oral argument on a motion. Further, Petitioner specifically states it is waiving its right to a hearing, not an oral argument on a motion. Construing the waiver as a waiver of an oral hearing on the merits is consistent with Petitioner's stated desire to expedite a decision to avoid the adverse financial impact of waiting for an oral hearing and subsequent decision on the merits. Given the resolution of this case, Petitioner suffers no prejudice by my construction of its waiver as a waiver of the right to an oral hearing rather than a waiver of oral argument on a motion.

alleged claims that were the bases for the initial determination are properly before me. Therefore, review of the evidence is necessary to attempt to resolve this question as a preliminary matter. Review of the evidence is also necessary for evaluation of the CMS motion to dismiss. In reviewing the evidence, it may be helpful to recall that the legal basis for revocation cited by Novitas and CMS is 42 C.F.R. § 424.535(a)(8), which provides:

> *Abuse of billing privileges*. The provider or supplier submits a claim or claims for services that could not have been furnished to a specific individual on the date of service. These instances include but are not limited to situations where the beneficiary is deceased, the directing physician or beneficiary is not in the State or country when services were furnished, or when the equipment necessary for testing is not present where the testing is said to have occurred.

a. The CMS Evidence

The CMS evidence is discussed chronologically to ensure the context is clear for each document and each action by Novitas.

> • CMS Ex. 3 – February 26, 2013 – AdvanceMed, a Medicare Zone Program Integrity Contractor (ZPIC),[8] notified Petitioner of "a potential violation of Medicare law, regulations and policies identified during a review of [Petitioner's] books of billing, and to provide [Petitioner] with the opportunity to review and respond to this information." CMS Ex. 3 at 1. The AdvanceMed notice referred Petitioner to 42 C.F.R. § 424.535(a)(8), suggesting that the potential violations identified by AdvanceMed may cause CMS to revoke Petitioner's Medicare participation. The letter alleges that a data analysis was conducted on claims submitted by Petitioner for the period January 1, 2008 through November 30, 2012. The data analysis allegedly identified 237 unique claims for services delivered to 114 unique deceased beneficiaries, on 211 unique dates of service. The letter refers to an attached spreadsheet listing the claims. The letter granted Petitioner 21 days to respond and advised that if Petitioner failed to respond or the response was not adequate to show compliance, the matter could be referred to CMS for additional action including revocation of Petitioner's billing privileges.

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[8] The notice letter advised Petitioner that AdvanceMed was the ZPIC for Part B services in Louisiana pursuant to a contract with CMS to fulfill program integrity functions for Medicare, specifically the reduction of fraud, waste, and abuse of Medicare funds. CMS Ex. 3.

CMS Ex. 3. The spreadsheet attached actually lists 24 claims with billed dates of service from January 4, 2008 through August 8, 2012. It is not important for this decision to resolve the discrepancy between my count and that reflected in the AdvanceMed letter.

• CMS Ex. 4 – March 21, 2013 – Counsel for Petitioner responded to the February 26, 2013 notice from AdvanceMed. The letter states that counsel enclosed a binder, organized by beneficiary and in the same order as the spreadsheet that accompanied the AdvanceMed notice, as well as an annotated copy of the spreadsheet. Petitioner's letter indicates that the same information was faxed to AdvanceMed as AdvanceMed requested in the notice. Petitioner explained in its letter how it received and processed orders for laboratory testing; the process for completing requisition forms for phlebotomists to draw blood; the process for the phlebotomist to draw nursing home residents' blood; the fact that Petitioner processed 300 to 400 requisitions per day; the process for delivery to the laboratory; the process for reporting results; and the process of delivering information to an outside billing company. Counsel for Petitioner included in his letter a table explaining for each beneficiary the billing or other error that occurred. For some of the beneficiaries, counsel explained that Petitioner had insufficient data to determine where a billing error occurred, and, for that reason, counsel stated that he had requested remittance forms and explanations of benefits (EOBs) from Novitas for all the beneficiaries and dates of service. Counsel stated in his letter that all documents had been numbered for ease of reference and that an electronic version of the documents was being provided. Petitioner's table lists the following 24 beneficiaries and 27 claims with the notation "insufficient data": Donald M.; Elizabeth M.; James W.; Bobby G.; Ronald C.; Neil M.; Ruby G.; James C.; Ida C. (possible explanation provided); Willis H.; Billie W.; Gladys J.; Irene R.; Mary B. (two entries); Barbara E.; Dorothy B.; Argarette M. (two entries); Narvis H. (two entries); Annie W.; Dorothy W.; Mary H.; Gladys N.; Ben M.; and Ronald B. CMS Ex. 4.

The Prehearing Order dated September 19, 2013, ¶ II.D.1, directed that CMS file:

> Copies of its proposed exhibits marked and identified in accordance with the CRDP [Civil Remedies Division Procedure] and this Order. The first CMS exhibit will be a copy of the decision that is challenged with copies of the evidence considered by the hearing officer or official who made the reconsideration decision attached, with all pages of the exhibit numbered consecutively beginning with "1."

The reconsideration decision marked as CMS Ex. 1 at 2-5, states that the reconsideration hearing officer considered "evidence in the file." CMS Ex. 1 at 2. The documents

referred to by counsel for Petitioner in his March 21, 2013 response to AdvanceMed were not submitted as evidence by CMS as part of CMS Ex. 1 or CMS Ex. 4. In fact, the letter from Novitas to counsel for CMS dated October 2, 2013, which appears to have been forwarding the file considered on reconsideration, makes no reference to Petitioner's letter dated March 21, 2013, or the documents submitted by Petitioner with that letter. Rather than conclude that CMS intentionally or negligently violated my Prehearing Order, I infer, based on the October 2, 2013 letter, that Petitioner's March 21, 2013 letter and supporting documents were not considered by Novitas on reconsideration or on the initial determination and that explains why those documents have not been submitted by CMS for my consideration.

> • CMS Ex. 5 – May 23, 2013 – On this date, Minisha C. Hicks, CMS, Provider Enrollment Operations Group, sent an email, with attachment, to various individuals directing revocation of Petitioner's billing privileges and directing "Zone 5," which I infer refers to the ZPIC AdvanceMed, to send a CD with the "additional supporting documentation ASAP." CMS Ex. 5 at 1. Ms. Hicks states in her email that the revocation is based on the attached document which is an undated "Referral for Revocation" from AdvanceMed. CMS Ex. 5 at 2-6. The referral for revocation refers to five attachments, including confirmation of the dates of death and Petitioner's March 21, 2013 response to the February 26, 2013 AdvanceMed notice on CD. However, CMS has filed none of these enclosures for my consideration. The legal basis for revocation cited by AdvanceMed is 42 C.F.R. § 424.535(a)(8). The revocation referral states in the section titled "Application of Facts to Revocation Reason:" "AdvanceMed has identified 237 claims submitted by Doctor's Lab (31 claims have no adequate explanation) for deceased beneficiaries since January 1, 2008." CMS Ex. 5 at 5.

I conclude that the only reasonable reading of this document is that AdvanceMed identified 237 questionable claims and requested an explanation from Petitioner. AdvanceMed concluded that Petitioner provided an adequate explanation for all but 31. Therefore, the basis for the referral for revocation was 31 inadequately explained claims. The AdvanceMed "Referral for Revocation" does not list or otherwise identify the 31 claims or any details related to those claims.

> • CMS Ex. 6 – Letter dated May 30, 2013, from Novitas to Petitioner notifying Petitioner that its billing privileges were being revoked June 29, 2013, based on 42 C.F.R. § 424.535(a)(8). The letter states:
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> > The Medicare supplier Drs Lab/D & G Holdings LLC has violated standards to maintain enrollment with the Medicare program. Doctor's Lab/D & G Holdings LLC submitted claims for lab services and mileage for 114 deceased beneficiaries on 211 unique dates of service and 237 claims

> between January 1, 2008 and December 31, 2012. Doctor's Lab/D & G Holdings LLC was given an opportunity to review the claims for these beneficiaries. However, it failed to provide an explanation for 26 deceased beneficiary claims.

CMS Ex. 6 at 1. The notice advised Petitioner that re-enrollment was barred for two years and that Petitioner had the right to request reconsideration. The notice does not cite to specific beneficiaries, specific claims, or specific dates. The notice does not list the "26 deceased beneficiary claims" on which the decision was based or clarify whether it was claims related to 26 deceased beneficiaries or 26 claims related to deceased beneficiaries. The allegation that mileage claims were involved is clearly in error based on the AdvanceMed Referral for Revocation, which states that mileage claims had been referred to the Inspector General. CMS Ex. 5 at 3. The AdvanceMed Referral for Revocation also clearly stated that it was based on claims for services to deceased beneficiaries. CMS Ex. 5 at 3-5.

Considering the notice of initial determination to revoke Petitioner's billing privileges in the context of the preceding documents, the only reasonable reading is that Novitas based the decision to revoke on 26 claims or beneficiaries that Petitioner did not adequately explain. There is no clue why AdvanceMed cited 31 claims (CMS Ex. 5 at 5) and Novitas cites only 26 claims or beneficiaries (CMS Ex. 6 at 1). However, it is not necessary for this decision that I resolve the inconsistency.[9]

> • CMS Ex. 7 – Letter dated July 15, 2013, from Petitioner to Novitas requesting reconsideration of the initial determination dated May 30, 2013. Petitioner states that it understands the revocation was based on its failure to explain claims made for 26 deceased beneficiaries between January 1, 2008 and December 31, 2012. Petitioner denies that it abused its billing privileges by billing for deceased beneficiaries. Petitioner states that it twice requested that Novitas provide the documents related to the alleged errors, on March 8, 2013 and June 12, 2013, and that it was advised on June 25, 2013, that Novitas was collecting the documents and that they would be released within the week, but no documents had been released. Petitioner expressly reserved the right to supplement its reconsideration request after the documents were produced by Novitas. CMS Ex. 7.

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[9] Petitioner's March 21, 2013 response to AdvanceMed listed 24 beneficiaries with 27 claims for which Petitioner stated it had insufficient data to identify the cause of a billing or other error. CMS Ex. 4.

• CMS Ex. 1 at 2-5 – On August 13, 2013, the reconsideration determination was issued by the Novitas Hearing Officer. The Hearing Officer determined that the request for reconsideration was timely. The Hearing Officer discussed in the reconsideration determination that Petitioner advised her of the pending request by Petitioner for the records underlying the alleged abusive billing claims, and she acknowledged that she had evidence that the request for records had been made and that release was forthcoming, but she dismisses the issue, stating that Petitioner's former billing company should have had the records, despite Petitioner's representation to the contrary. CMS Ex. 1 at 3. The Hearing Officer acknowledged that AdvanceMed concluded that Petitioner had not adequately explained billing for 31 unique deceased beneficiaries. The Hearing Officer does not specifically discuss the reference in the May 30, 2013 initial determination to the "26 deceased beneficiary claims" or attempt to determine whether the initial determination referred to claims related to 26 deceased beneficiaries or 26 claims related to deceased beneficiaries. The Hearing Officer's decision states:

> D&G Holdings, LLC/Drs Lab has not provided evidence to show full compliance with the standards for which they were revoked. Therefore, we cannot grant you access to the Medicare Trust Fund (by way or issuance) of a Medicare number.

CMS Ex. 1 at 4.

The Hearing Officer does not cite to specific beneficiaries, specific claims, or specific dates that support a conclusion that Petitioner abused its billing privileges. In fact, the Hearing Officer does not specifically state that she concluded that Petitioner abused its billing privileges.

• CMS Ex. 8 – The December 20, 2013 Declaration of Cindy White, a Business Analyst, IV with Novitas, was filed with the CMS Reply on December 20, 2013. Ms. White testifies that she researched claims for services submitted by Petitioner between January 28, 2008 and February 26, 2012, which is a different period than that originally identified by AdvanceMed. She prepared a spreadsheet which was attached to her declaration. The spreadsheet lists 37 claims for 30 beneficiaries. The first four are for beneficiaries for whom Petitioner advised AdvanceMed that it had insufficient information about the claims. Ms. White also could find no information for those claims. CMS Ex. 8 at 2-3, 7. She did find information for 33 other claims, including information for 11 claims for 8 beneficiaries not previously included among those identified by Petitioner. Ms. White testifies that 32 of the claims listed on her spreadsheet were denied automatically because the date of service was a date after the beneficiary's date of death. CMS Ex. 8 at 3.

None of the documents that Ms. White considered when creating her spreadsheet have been offered as evidence by CMS for my de novo review.

b. The CMS motion to dismiss is not well-founded and must be denied.

CMS moved to dismiss this case on October 28, 2013. CMS argued in its motion that Petitioner's billing privileges and participation in Medicare were revoked because Petitioner submitted 237 claims for 114 deceased beneficiaries, but Petitioner requested ALJ review as to only 26 of the 237 claims. CMS reasons, therefore, that Petitioner did not request review as to 211 claims for services to "dead beneficiaries;" the Novitas findings and conclusions as to the 211 claims are administratively final; the 211 unchallenged claims are an adequate bases for revocation pursuant to 42 C.F.R. § 424.535(a)(8); and Petitioner's request for review should be dismissed. CMS MTD.

Petitioner filed an opposition to the CMS motion to dismiss on November 13, 2013. Petitioner argues that the CMS motion to dismiss should be denied. Petitioner argues that CMS is in error in its reading of the May 23, 2013 referral for revocation (CMS Ex. 5); the notice of initial determination dated May 30, 2013 (CMS Ex. 6); and the August 13, 2013 reconsideration determination (CMS Ex. 1 at 2-5). Petitioner argues that the initial determination states that the revocation of Petitioner's billing privileges and participation in Medicare pursuant to 42 C.F.R. § 424.535(a)(8) was based on 26 claims related to 23 beneficiaries who were allegedly deceased when services were claimed to have been delivered. Petitioner notes that its interpretation of the initial denial is supported by the referral for revocation, which alleged 31 claims as the basis for revocation.[10] Petitioner argues that the reconsideration determination also reflects that the basis for revocation was only 26 claims and not the original 237 claims questioned by AdvanceMed. Petitioner states that it requested a hearing based upon its reasonable interpretation of the notice of the initial determination and reconsideration determination. P. Opp. MTD.

CMS is required to ensure that a notice of initial determination is mailed to the affected party, in this case Petitioner, and the notice must set forth: the basis or reasons for the determination; the effect of the determination; and the affected party's right to reconsideration or a hearing. 42 C.F.R. § 498.20. CMS is also responsible to ensure that a notice of the reconsideration determination is mailed to the affected party. The notice must give the reasons for the determination; if the determination is adverse, the notice must specify the requirements of law or regulations that the affected party failed to meet; and it must inform the affected party of the right to a hearing. 42 C.F.R. § 498.25(a).

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[10] Petitioner states that it is also unable to explain why the referral for revocation refers to 31 claims but the initial determination refers to 26. P. Opp. MTD at 2-3.

The notices of the initial and reconsideration determinations have been described in the discussion of the CMS evidence set forth above and there is no need to repeat their content here. In this case, the notice of initial determination dated May 30, 2013, from Novitas to Petitioner, advised Petitioner that revocation was based on Petitioner's failure to explain "26 deceased beneficiary claims." CMS Ex. 6 at 1. The notice of the reconsideration determination dated August 13, 2013, is vaguer than the notice of initial determination. However, reading the two notices together, I conclude that the intent of the reconsideration hearing officer was to simply uphold the initial determination which was based on 26 deceased beneficiary claims. CMS Ex. 1 at 2-5.

I conclude that Novitas did not revoke Petitioner's billing privileges based on 237 claims as alleged by CMS. Rather, Petitioner's construction of the initial and reconsideration determinations is correct and the revocation was based on 26 deceased beneficiary claims.[11] Accordingly, I conclude that the CMS motion to dismiss is without merit and must be denied.

c. Analysis of the CMS case on the merits.

It is 42 C.F.R. § 424.535(a)(8) that authorizes CMS to revoke Medicare enrollment and billing privileges for the abuse of billing privileges. Abuse of billing privileges is described as follows:

> (8) *Abuse of billing privileges*. The provider or supplier submits a claim or claims for services that could not have been furnished to a specific individual on the date of service. These instances include but are not limited to situations where the beneficiary is deceased, the directing physician or beneficiary is not in the State or country when services were furnished, or when the equipment necessary for testing is not present where the testing is said to have occurred.

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[11] Because Novitas did not provide a list of the specific 26 deceased beneficiary claims in either the initial or reconsideration determination, Petitioner has been left to guess which 26 deceased beneficiary claims are truly at issue. Arguably, CMS has failed to satisfy the regulatory requirement for adequate notice to Petitioner of the basis for the adverse action in this case and, that alone, should justify resolving this case against CMS. However, Petitioner has not advanced that specific argument. Therefore, I do not resolve this case against CMS based on inadequate notice but proceed to address the even more egregious failing of CMS and its contractor in this case.

42 C.F.R. § 424.535(a)(8). This regulation provides Petitioner notice that billing privileges and Medicare enrollment may be revoked for an abuse of billing privileges. 5 U.S.C. §§ 551(4), 552(a)(1). The elements of the CMS prima facie case for revocation based on 42 C.F.R. § 424.535(a)(8), derived from the regulatory language, are: (1) the provider or supplier submits one or more claims for services; and (2) the services for which a claim or claims were submitted could not have been delivered to a Medicare beneficiary on the date the service was claimed to have been delivered. *Realhab, Inc.*, DAB No. 2542 at 16-17 (2013). Subsection 424.535(a)(8) was added to Title 42 as a basis for revocation of billing privileges by a final rule issued on June 27, 2008, with an effective date of August 26, 2008. 73 Fed. Reg. 36,448 (June 27, 2008). The regulatory history states that the subsection was proposed to permit Medicare contractors to revoke billing privileges when "a provider or supplier submits a claim or claims for services that could not have been furnished to a beneficiary." *Id*. at 36,450. The drafters state that it is "both appropriate and necessary that [CMS] have the ability to revoke billing privileges when services could not have been furnished by a provider or supplier." *Id*. at 36,455. "This revocation authority is not intended to be used for isolated occurrences or accidental billing errors. Rather, this basis for revocation is directed at providers and suppliers who are engaging in a pattern of improper billing." *Id*. The drafters state that revocation on this basis will not be issued absent sufficient evidence of abusive billing patterns and that billing privileges will not be revoked unless there are at least three instances where billings privileges have been abused. *Id*. The regulation does not specifically state that revocation is limited to cases where the evidence is sufficient to show a pattern of abusive billing. However, the regulatory history strongly states that that limitation was intended by the drafters. Therefore, I conclude that it is necessary for CMS to show as part of its prima facie case that there was more than one claim for a service that could not have been delivered.[12]

CMS asserts in it motion for summary judgment that it is Petitioner's responsibility to show that its billing privileges were erroneously revoked. But CMS also recognizes that it has the burden to make a prima facie showing before Petitioner is put to its proofs, citing *Hillman Rehab. Ctr.*, DAB No. 1611 (1997), *aff'd, Hillman Rehab. Ctr. v. United States,* No. 98-3789 (GEB), 1999 WL 34813783 (D.N.J. May 13, 1999). CMS MSJ at 5. In its reply brief, CMS cites 42 C.F.R. § 424.545(c) for the proposition that Petitioner

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[12] The drafters also state that only CMS and not a Medicare contractor will make the determination to revoke pursuant to 42 C.F.R. § 424.535(a)(8). 73 Fed. Reg. 36,448, 36,455. Both the initial and reconsideration determinations in this case were issued by the contractor, not CMS. The evidence does not show that CMS initiated or reviewed either action prior to issuance. Therefore, the CMS action in this case is inconsistent with its clearly articulated policy in the regulatory history of 42 C.F.R. § 424.535(a)(8).

bears the burden to show by documents and records that it meets enrollment requirements. CMS Reply at 12, 18. CMS does not acknowledge in its reply brief that it bears the initial burden of making a prima facie showing of a basis for the revocation of Petitioner's billing privileges. I conclude that 42 C.F.R. § 424.545(c) does not relieve CMS of its burden to make a prima facie showing.

Pursuant to 42 C.F.R. § 424.545(a), the procedures of 42 C.F.R. pt. 498 control my review and Board review in this case. Pursuant to 42 C.F.R. § 424.545(c), a provider or supplier must be able to demonstrate that it meets enrollment requirements and it must make available to CMS or its contractor any documents and records that "support the provision of this regulation and the Medicare enrollment application if requested by CMS or its agents." The regulatory history of 42 C.F.R. § 424.545(c) does not suggest that the drafters intended to change existing procedures under 42 C.F.R. pt. 498, whether those procedures were established by regulation or interpretive rules of the Board as reflected in prior decisions of the Board. 71 Fed. Reg. 20,754, 20,762 (Apr. 21, 2006) as amended by 73 Fed. Reg. 36,461 (Jun. 27, 2008). Rather, the plain language of 42 C.F.R. § 424.545(c) states that it applies only when CMS or its agents request documents and records from a supplier. ALJs and the Board are not CMS or its agents, and it must be concluded based on the plain language of 42 C.F.R. § 424.545(c), that the regulation does not control in adjudications by ALJs or the Board.

The CMS acknowledgment that it bears the initial burden of making a prima facie showing of the basis for revocation is consistent with prior decisions of the Board that interpret the application of the Act and regulations in the adjudication of cases subject to 42 C.F.R. pt. 498. The Board decisions mentioned are Medicare enforcement cases related to long-term care facilities which are subject to 42 C.F.R. pt. 498. The Board has consistently concluded that the hearing before an ALJ under 42 C.F.R. pt. 498 is a de novo proceeding, i.e.,"a fresh look by a neutral decision-maker at the legal and factual basis" for citations of statutory or regulatory violations that are the basis for CMS remedial enforcement actions. *Life Care Ctr. of Bardstown*, DAB No. 2479 at 33 (2012) (citation omitted). The standard of proof required is a preponderance of the evidence. CMS has the burden of coming forward with evidence sufficient to make a prima facie showing of a basis for the enforcement action. The quantum of evidence necessary for a prima facie showing is not specified in the regulations or specifically resolved by prior decisions of the Board. But, the Board has stated that CMS must come forward with "evidence related to disputed findings that is sufficient (together with any undisputed findings and relevant legal authority) to establish a prima facie case of noncompliance with a regulatory requirement." *Evergreene Nursing Care Ctr.*, DAB No. 2069 at 7 (2007); *Batavia Nursing and Convalescent Ctr.*, DAB No. 1904 (2004). "Prima facie" means generally that the evidence is "[s]ufficient to establish a fact or raise a presumption unless disproved or rebutted." *Black's Law Dictionary* 1228 (8th ed. 2004). In *Hillman Rehab. Ctr.*, the Board described the elements of the CMS prima facie case in general terms as follows:

> HCFA [now known as CMS] must identify the legal criteria to which it seeks to hold a provider. Moreover, to the extent that a provider challenges HCFA's findings, HCFA must come forward with evidence of the basis for its determination, including the factual findings on which HCFA is relying and, if HCFA has determined that a condition of participation was not met, HCFA's evaluation that the deficiencies found meet the regulatory standard for a condition-level deficiency.

DAB No. 1611 at 8. Thus, CMS has the initial burden of coming forward with sufficient evidence to show that its decision to impose an enforcement remedy is legally sufficient under the statute and regulations. To make a prima facie case that its decision was legally sufficient, CMS must: (1) identify the statute, regulation or other legal criteria to which it seeks to hold the provider; (2) come forward with evidence upon which it relies for its factual conclusions that are disputed by the petitioner. In *Evergreene Nursing Care Ctr.*, the Board explained its "well-established framework for allocating the burden of proof on the issue of whether the SNF [skilled nursing facility] was out of substantial compliance" as follows:

> CMS has the burden of coming forward with evidence related to disputed findings that is sufficient (together with any undisputed findings and relevant legal authority) to establish a prima facie case of noncompliance with a regulatory requirement. If CMS makes this prima facie showing, then the SNF must carry its ultimate burden of persuasion by showing, by a preponderance of the evidence, on the record as a whole, that it was in substantial compliance during the relevant period.

Evergreene at 7. CMS makes a prima facie showing of noncompliance if the credible evidence CMS relies on is sufficient to support a decision in its favor absent an effective rebuttal.

There is no dispute in this case that at the time of the attempted revocation by Novitas, Petitioner was enrolled in Medicare as a supplier with billing privileges. The Secretary has delegated authority to CMS to revoke a supplier's or provider's billing privileges for any of the reasons listed in 42 C.F.R. § 424.535(a). CMS relies upon 42 C.F.R. § 424.535(a)(8), which establishes abuse of billing privileges as a basis for the revocation of enrollment and billing privileges. As previously mentioned, 42 C.F.R. § 424.535(a)(8) involves three elements: (1) Petitioner submitted claims for Medicare payment for services to Medicare beneficiaries; (2) the services for which claims were submitted could not have been provided to a Medicare beneficiary; and (3) more than one such

claim was submitted. CMS has the burden of coming forward with evidence related to any of its findings that are disputed by Petitioner, sufficient to amount to a prima facie showing.

AdvanceMed first sent Petitioner a letter dated February 26, 2013, advising Petitioner that a data analysis had been done for Petitioner's claims from January 1, 2008 through November 30, 2012, which allegedly identified 237 claims related to 114 deceased beneficiaries on 211 dates of service. Petitioner was provided a spreadsheet that listed the claims by beneficiary, date of death, claim number, and date of service. Petitioner was given 21 days to explain each claim and show compliance. CMS Ex. 3; P. Ex. 1. Petitioner responded on March 21, 2013, with a binder of evidence that CMS has not presented to me. Petitioner's response to AdvanceMed indicated that Petitioner had insufficient information to explain 27 claims related to 24 beneficiaries listed on the AdvanceMed spreadsheet. Petitioner advised AdvanceMed that it had requested documentation from Novitas for each of the claims and beneficiaries for which Petitioner had insufficient information. CMS Ex. 4. The "Referral for Revocation," which was attached to a May 23, 2013 email from a CMS representative, referred to 31 claims that had no adequate explanation and also referred to attached documents which CMS has also failed to present to me. The 31 claims are not specifically identified by the "Referral for Revocation" offered as evidence by CMS. CMS Ex. 5. Petitioner denied that it abused its billing privileges by billing for claims for services to deceased Medicare beneficiaries in its request for reconsideration dated July 15, 2013. Petitioner also stated that Novitas had yet to respond to its request for records related to the claims in issue. CMS Ex. 7. The August 13, 2013, reconsideration determination does nothing to clarify which claims are at issue or what evidence supports the alleged abuse of billing privileges by Petitioner. In its September 13, 2013 request for hearing, Petitioner continued to dispute that any facts show that it abused its billing privileges by filing claims for services that could not have been delivered to Medicare beneficiaries.

I conclude based on my review of the CMS evidence that CMS has failed to come forward with evidence, credible or otherwise, that supports the Novitas determinations that Petitioner filed any claims for services that could not have been delivered to Medicare beneficiaries. CMS Ex. 3, which includes a list of beneficiaries, dates of death, claim numbers, and dates of service and the letter from AdvanceMed to Petitioner, constitutes mere allegations of improper claims. CMS presents no evidence such as actual claim forms, requests for reimbursement, death certificates, or other evidence of death to show that claims were actually filed for deceased beneficiaries.[13] There is no

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[13] Civil Remedies Division Procedure (CRDP) 10 specifically discusses the use of summaries when a party wishes an ALJ to consider the content of records that are too voluminous to be conveniently examined in court. CRDP 10 is based on Fed. R. Evid.
(Footnote continued next page.)

dispute that Petitioner has consistently requested the underlying evidence since AdvanceMed first made its allegations known to Petitioner. CMS Ex. 4 is Petitioner's response to the allegations of AdvanceMed. Although Petitioner clearly states in its response that it has "insufficient data" to respond to the AdvanceMed allegations as to some beneficiaries and claims, Petitioner clearly did not admit that the allegations were founded or that the alleged claims were for services allegedly delivered after the date of death of the Medicare beneficiary. Petitioner made clear in its response that it had requested documentation from Novitas so that it could respond to the allegations but no documents had been received. CMS Ex. 4 at 2. CMS Ex. 5, the "Referral for Revocation," also sets forth mere allegations, particularly given the absence of any such substantive evidence as may have been in the referenced attachments that have not been filed by CMS for my consideration. The initial determination dated May 30, 2013, sets forth the findings and conclusions of Novitas, but does not include any substantive evidence of the actual claims on which the Novitas findings and conclusions were based. CMS Ex. 6. The reconsideration determination also does not reference any substantive evidence of the actual claims that underlie the initial and reconsideration determinations. CMS Ex. 1. In fact, neither determination actually lists the specific claims on which the determination is based. CMS Ex. 8 includes another list of claims but the list is for a different period of time, January 28, 2008 through January 19, 2012. No documents of the actual claims or that reflect that the beneficiaries allegedly involved were deceased were submitted for my review. Therefore, CMS has not presented substantive evidence as to specific claims for services delivered to Medicare beneficiaries or demonstrated that those claimed services could not have been delivered because the beneficiary was deceased at the time the service was claimed to have been delivered. CMS has thus failed to make a prima facie showing as to the elements of 42 C.F.R. § 424.535(a)(8).

The failure of CMS to present evidence as to disputed findings and to meet its burden to make a prima facie showing is fatal to the CMS case. I also note that the CMS approach in this case prevents me from conducting a de novo review of the bases for the revocation of Petitioner's billing privileges and deprives Petitioner of any meaningful review – a

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(Footnote continued.)

1006. CRDP 10 and Fed. R. Evid. 1006 are rules of evidence that permit the admission of a summary in lieu of voluminous records for convenience. CRDP 10 does not relieve CMS of its burden to make a prima facie showing of a basis for its adverse action. CMS has not submitted the documents that show claims were made or that beneficiaries were deceased at the time services were claimed to have been delivered or asserted that such documents are voluminous. I note that an important requirement for the use of such summaries stated in both CRDP 10 and Fed. R. Evid. 1006 is that the offering party must provide the opposing party with copies of all supporting documents on which the summary is based.

deprivation of the review process intended by Congress and the Secretary that may not be overlooked.

My review of Petitioner's request for hearing, motion for summary judgment, opposition to the CMS motion to dismiss, opposition to the CMS motion for summary judgment, and reply to the CMS opposition to Petitioner's motion for summary judgment, shows that Petitioner does not concede any improper or incorrect billing that could be characterized as abusive within the meaning of 42 C.F.R. § 424.535(a)(8).[14] Rather, Petitioner's pleadings are extremely persuasive that AdvanceMed and Novitas were in error as to nearly all claims they cited and Petitioner has a credible explanation for the remaining claims – that there were simple billing errors and not an abuse of billing privileges. A brief review of Petitioner's evidence is appropriate to verify that Petitioner did not concede a basis for revocation of its enrollment and billing privileges. P. Ex. 1 is a copy of the AdvanceMed letter dated February 26, 2013, which is also in evidence as CMS Ex. 3. P. Ex. 2 is a document which reflects a transition from Pinnacle Business Solutions, Inc. to Novitas in 2012, and is not related to any alleged improper claims by Petitioner. P. Ex. 3 is the March 8, 2013 request from Petitioner to Novitas for the release of documents related to the list of claims attached to the AdvanceMed letter dated February 26, 2013 (P. Ex. 1; CMS Ex. 3). P. Ex. 3 contains no admissions that any claims were improper. P. Ex. 4 is a March 15, 2013 letter from Novitas denying Petitioner's March 8, 2013 request for documents. P. Ex. 5 is Petitioner's March 21, 2013 response to the AdvanceMed letter dated February 26, 2013. Another copy of Petitioner's March 21, 2013 response is also in evidence as CMS Ex. 4. P. Ex. 6 is a copy of the May 30, 2013 Novitas initial determination to revoke, which is also in evidence as CMS Ex. 6. P. Ex. 7 is Petitioner's June 12, 2013 request for documents from Novitas, which includes no admissions that Petitioner filed improper claims. P. Ex. 8 is Petitioner's July 15, 2013, request for reconsideration, a copy of which is also in evidence as CMS Ex. 7. P. Ex. 9 is Petitioner's July 25, 2013 request that Novitas expedite its response to Petitioner's request for records. P. Ex. 10 is a copy of the August 13, 2013 reconsideration determination, which is also in evidence as CMS Ex. 1 at 2-5. P. Ex. 11 is the August 16, 2013 response of CMS to Petitioner's request for records with documents containing claims information attached. P. Ex. 12 is a copy of the CMS publication "Understanding the Remittance Advice: A Guide for Medicare Providers, Physicians, Suppliers, and Billers" (3d ed. Oct. 2010). P. Ex. 13 is a collection of Medicare Remittance Notices from Pinnacle. P. Ex. 14 is a collection of laboratory request forms and reports. P. Exs. 15, 16, 18, 30, and 31 are declarations of various individuals explaining the billing process and claims related to the beneficiaries that

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[14] This case is distinguishable from *Realhab, Inc.*, DAB No. 2542, in which the petitioner's evidence demonstrated the regulatory violation relied upon by CMS as the basis for revocation.

Petitioner has identified as being at issue in support of Petitioner's position and rebutting the CMS allegation that claims were abusive. P. Ex. 17 is a chart or table that lists the claims Petitioner has identified as being at issue and sets forth Petitioner's explanation for why the claims are not abusive. P. Exs. 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, and 29 are requisition forms, reports, and other medical records related to individual beneficiaries that Petitioner identified as being involved. My review of Petitioner's evidence discloses no admission that any claims identified by AdvanceMed demonstrated abusive billing.

Accordingly, I conclude that CMS has merely alleged but failed to make a prima facie showing that Petitioner abused its billing privileges within the meaning of 42 C.F.R. § 424.535(a)(8).

III. Conclusion

For the foregoing reasons, I conclude that CMS has failed to establish a basis for the revocation of Petitioner's Medicare enrollment and billing privileges.

/s/
Keith W. Sickendick
Administrative Law Judge