Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Med-Care Diabetic & Medical Supplies, Inc.
Docket No. A-16-117
Decision No. 2764
January 17, 2017

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Petitioner Med-Care Diabetic & Medical Supplies, Inc. (Med-Care, Petitioner), appeals the May 20, 2016 decision of an administrative Law Judge (ALJ) sustaining the revocation of Petitioner's Medicare billing privileges. *Med-Care Diabetic & Medical Supplies, Inc.*, DAB CR4615 (2016) (ALJ Decision). The Centers for Medicare & Medicaid Services (CMS), Center for Program Integrity (CPI), revoked Petitioner's Medicare enrollment and billing privileges, pursuant to Title 42 of the Code of Federal Regulations (C.F.R.), section 424.535(a)(8), because Petitioner, a supplier of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) to Medicare beneficiaries, submitted claims for items provided to beneficiaries who were deceased on the purported dates of service between January 8, 2012 and May 16, 2015. In addition, CMS imposed a bar of three years on Petitioner's eligibility to re-enroll in the Medicare program. The ALJ determined there was no material factual dispute that Petitioner failed to comply with the regulation at 42 C.F.R. § 424.535(a)(8) and granted summary judgment for CMS, upholding revocation. For the reasons explained below, we sustain the ALJ Decision.

Applicable legal authorities

The Social Security Act (the Act) provides for CMS to regulate the enrollment of providers and suppliers in the Medicare program. Act § 1866(j) (1)(A); 42 U.S.C. § 1395cc(j)(1)(A).

The term "supplier" means, unless the context otherwise requires, a physician or other practitioner, a facility, *or other entity* (other than a provider of services) *that furnishes items or services* under the Act. Act § 1861(d) (emphasis added).

A DMEPOS supplier is an entity or individual that sells or rents Part B covered DMEPOS items to Medicare beneficiaries and which meets the DMEPOS supplier standards. *See* 42 C.F.R. § 424.57.

The regulations in 42 C.F.R. Part 424, subpart P set out the requirements for establishing and maintaining Medicare billing privileges. In order to receive payment for items or services furnished to Medicare beneficiaries, a provider or supplier must be "enrolled" in Medicare and maintain active enrollment status. 42 C.F.R. §§ 424.500, 424.505, 424.510, 424.516. The regulation at 42 C.F.R. § 424.535(a) states that CMS may revoke a provider's or supplier's Medicare billing privileges and any corresponding provider or supplier agreement for various reasons. Among those reasons, relevant here, section 424.535(a)(8)(i)(A) states:

> (8) *Abuse of billing privileges*. Abuse of billing privileges includes . . .
>
> (i) 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 the following situations:
>
> (A) Where the beneficiary is deceased.[1]

The preamble to the final rule publishing this section states:

> 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 … We believe that it is both appropriate and necessary that we have the ability to revoke billing privileges when services could not have been furnished by a provider or supplier. We recognize the impact that this revocation has, and a revocation will not be issued unless sufficient evidence demonstrates abusive billing patterns. Accordingly, we will not revoke billing privileges under § 424.535(a)(8) unless there are multiple instances, at least three, where abusive billing practices have taken place … In conclusion, we believe that providers and suppliers are responsible for the claims they submit or the claims submitted on their behalf. We believe that it is essential that providers and suppliers take the necessary steps to ensure they are billing appropriately for services furnished to Medicare beneficiaries.

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[1] The conduct cited in the revocation action occurred between January 2012 and May 2015. This subsection was substantially revised effective February 3, 2015 (79 Fed. Reg. 72,500, 72,532) (Dec. 5, 2014), and we apply the regulation as in effect at the time of the notice of revocation (November 12, 2015). Accordingly, we apply the revised regulation to all of the claims cited in the revocation notice. The revised text of the regulation, last viewed on January 11, 2017, is available here: http://www.ecfr.gov/cgi-bin/text-idx?node=se42.3.424_1535&rgn=div8

73 Fed. Reg. 36,448; 36,455 (June 27, 2008).

If CMS revokes a supplier's billing privileges, the supplier is "barred from participating in the Medicare program from the date of the revocation until the end of the re-enrollment bar." 42 C.F.R. § 424.535(c).[2] The re-enrollment bar must last for a minimum of one year but may not exceed three years, "depending upon the severity of the basis for revocation." *Id.* Revocation also results in the termination of the provider's or supplier's agreement with Medicare. *Id*. § 424.535(b).

A supplier whose Medicare enrollment has been revoked may request reconsideration by CMS or its contractor, and then appeal the reconsideration decision in accordance with the procedures at 42 C.F.R. Part 498. 42 C.F.R. §§ 424.545(a), 498.3(b)(17), 498.5(l)(1)-(3), 498.22(a), 498.24; 498.40, 498.80.

Case Background[3]

Between January 2012 and May 2015, Med-Care filed Medicare reimbursement claims for various DMEPOS furnished to beneficiaries who were on record as deceased on the dates of service. CMS Exs. 1; 3; 4 at ¶ 6. CMS revoked Petitioner's Medicare enrollment and billing privileges under the regulation at 42 C.F.R. § 424.535(a)(8) for abuse of billing privileges. In its notice to Med-Care dated November 12, 2015, CMS describes Med-Care's abuse of billing privileges, stating in pertinent part:

> **42 CFR § 424.535(a)(8)(i) - Abuse of Billing**
>
> Data analysis conducted on claims submitted by Med-Care Diabetic & Medical Supplies, Inc. revealed claims for items provided to 316 beneficiaries who, per the Social Security Administration Death Master file, were deceased on the purported date of service. These claims were refills of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) with dates of service between January 8, 2012 and May 16, 2015. Per the Medicare Provider Enrollment Integrity Manual, Chapter 4, Section 4.26.1, the supplier must contact the beneficiary to ensure that items are necessary prior to dispensing products that are supplied as refills to an original order. This contact must take place no sooner that 14

[2] While we note that CMS has issued a Proposed Rule which would increase the maximum reenrollment bar from 3 years to 10 years (with certain exceptions) (81 Fed. Reg. 10,720, 10,732, 10,746 (Mar. 1, 2016)), we apply the regulation as in effect at the time of the revocation.

[3] Background information is drawn, unless otherwise indicated, from the ALJ Decision and the record before the ALJ and is not intended to substitute for his findings.

> calendar days prior to the delivery/shipping date. The beneficiaries' dates of death on the above referenced claims were at least 15 days prior to the date of service. According to the Medicare Claims Processing Manual, Chapter 20, Section 110.3.2, for DMEPOS, the general rule is that the date of service is equal to the date of delivery. Accordingly, the beneficiaries were deceased on the dates of service and prior to the 14 day contact window described above. Please see the attached claims data.

CMS Ex. 1, at 1. CMS also notified Petitioner that it could request reconsideration within 60 days, and "submit additional information with the reconsideration that you believe may have a bearing on the decision." *Id*. at 2. Med-Care's timely reconsideration request followed.

CMS upheld revocation on reconsidered determination. CMS Ex. 2. In its decision letter, CMS stated, in pertinent part:

> All of the documentation in the file for Med-Care has been reviewed and the decision has been made in accordance with Medicare guidelines, as outlined in 42 CFR §424.535. Med-Care has been revoked for abuse of billing privileges. . . . [D]ata analysis conducted on claims submitted by Med-Care revealed claims for items provided to 316 beneficiaries who, per the Social Security Administration Death Master File, were deceased on the purported date of service. From the time period of January 1, 2012 to December 30, 2014 CMS identified 2,510 claim lines where Med-Care submitted multiple dates of service for a beneficiary that [was] already dead at the time the service took place. This analysis only identified where Med-Care submitted more than one service on a different date to the beneficiary post date of death. Med-Care submitted claims for some beneficiaries seven or more dates of service post date of death.

CMS Ex. 2, at 2-3.

Med-Care filed a timely request for ALJ hearing (Request for Hearing, RFH) disputing CMS's reconsidered determination and arguing that the initial revocation determination lacked both legal and factual bases. RFH at 1-2. Med-Care argued that the regulatory provision under which CMS revoked Petitioner's Medicare enrollment and billing privileges applies only to "in person services," and not to "mail-order" suppliers such as Med-Care. *Id*. at 4-5. Med-Care's argument, in essence, is that the preamble to the final rule reflects CMS's intention for 42 C.F.R. § 424.535(a)(8) to "target circumstances where providers billed for services that are performed in person when it was not possible for the in-person contact to have occurred." *Id*. at 4. In its Request, Med-Care set forth its rationale for this interpretation of the regulation this way:

> [T]he agency's preamble discussion of this authority focuses on physicians services, which clearly could not have been performed in instances where a beneficiary has died prior to the date of service. In contrast to the situation described in the preamble language [. . .] involving ***in person services***, CMS has alleged in the present revocation action that durable medical equipment ("DME") items shipped via the mail were billed improperly. The process for furnishing such mail order items and submitting claims significantly differs from those applicable to in person services. Suppliers such as Petitioner have no in person contact with the beneficiary to whom they furnish items, typically performing the tasks related to an order via telephone communication.

Id. at 5. Med-Care reasoned that, in view of the guidance CMS issued via its Medicare Program Integrity Manual (MPIM), which requires a DMEPOS supplier to contact the beneficiary or the beneficiary's designee via telephone and ensure that an item is necessary before providing refills, an "element of impossibility, inherent to an in person service, does not apply to a shipment of diabetic supplies based on telephone communication with a beneficiary's designee." *Id*.

Med-Care also contended that CMS's initial determination was based upon factual inaccuracies and founded upon insufficient and previously undisclosed evidence. *Id*. at 6. For example, Med-Care argued that claims for only 299, rather than 316 beneficiaries, were at issue. *Id*. In addition, Med-Care denied receiving timely notice of CMS's reliance on data involving 2,510 claim submissions as the basis for revocation, and that the lack of notice violated Med-Care's due process rights. *Id*. at 2, 6-7. Med-Care also contended that CMS abused its discretion by confusing terminology – specifically, conflating the term "claims" with the term "claim lines." *Id*. at 7. Further, Med-Care contended that its evidence refutes CMS's charge of abusive billing, citing documented contact with beneficiaries or designees prior to shipping refills, and conducting beneficiary eligibility checks "via Medicare's own system." *Id*. at 2. Med-Care contended that as a consequence of its "comprehensive policies" with "multiple safeguards to ensure proper billing of claims[,]" no "claim for a deceased beneficiary" was "paid in error" and thus "[t]here has been zero impact on the Medicare Trust fund." *Id*. Petitioner thus contended that it did not abuse its billing privileges. *See id*.

CMS moved for summary judgment, arguing that the material facts in the case – that "based upon data from the Social Security Administration, [. . .] over 300 claims submitted by Petitioner were for beneficiaries who were deceased. Petitioner has put forth no evidence that disputes this determination." CMS Motion for Summary Judgment (MSJ) at 1. The data upon which CMS relied were listed on a spreadsheet containing

beneficiaries' names, Health Insurance Claim (HIC) numbers (unique identifiers issued to Medicare beneficiaries), dates of death, dates of service, and the Healthcare Common Procedure Coding System (HCPCS)[4] code for the supply or equipment for which Petitioner billed Medicare. *See id*. at 3-4 n.2. CMS further argued that it was undisputed that Med-Care "submitted 78 claims for beneficiaries it knew were deceased," where, at the reconsideration stage of review, Med-Care had cited only "clerical error" in its defense. *Id*. at 3.

Med-Care replied to CMS's summary judgment motion first by listing several factual assertions, followed by two main arguments: 1) that CMS's motion was legally and factually inadequate because, among other reasons, section 424.535(a)(8) was inapplicable to mail order suppliers; and 2) that the revocation was without basis in law or in fact. Petitioner's Pre-Hearing Exchange & Response to MSJ at 2; 8; 10, 19-21. Petitioner also argued that good cause existed for the ALJ to admit new evidence. *Id*. at 23. Petitioner also argued that section 424.535(a)(8) was arbitrarily and capriciously applied to Med-Care, and that CMS failed to provide adequate proof of beneficiaries' deaths or dates of death to carry its burden on Summary Judgment. *Id*. at 2, 9, 11-12, 14, 20-21.

ALJ Decision

The ALJ sustained the revocation determination, granting summary judgment in favor of CMS. *See* ALJ Decision (Dec.). In reaching his decision, the ALJ admitted and considered all 20 evidentiary exhibits submitted by CMS, and all 7 exhibits submitted by Med-Care. ALJ Dec. at 1. The ALJ rejected Petitioner's contention that section 4242.535(a)(8) does not apply to mail-order suppliers such as Med-Care, stating, in pertinent part:

> Petitioner's principal argument is that the language of 42 C.F.R. § 424.535(a)(8) is inapplicable here. It contends that this regulation only makes sense in the context of alleged face-to-face transactions, such as a physician alleging to have provided a medical treatment to a beneficiary on a date when the beneficiary is deceased. It asserts that the regulation does not – or should not – apply to a business such as Petitioner's business, which is a mail order supply company. It asserts that it sells high volume products by mail and cannot reasonably be expected to know which of its customers (beneficiaries) are alive or dead. Thus, according to Petitioner, it should not be penalized for erroneous claims for sales to deceased

[4] HCPCS codes are a compilation of definitions of physician and other health care professional services, codes for those services and payment modifiers used to process and pay Medicare claims. *See* 42 C.F.R. §§ 414.2, 414.40; 45 C.F.R. § 162.1002.

> beneficiaries when it allegedly had safeguards in place to prevent this and was not in a position to know whether those beneficiaries were alive or dead on the dates of the claimed transactions. This argument fails, foremost, because the regulation does not distinguish between mail order and face-to-face transactions. There is no language in the regulation – and Petitioner has identified none – that carves out the exception that Petitioner demands. Indeed, Petitioner's argument that it should be given a free pass to claim reimbursement for services allegedly provided to dead people is brazenly contrary to the regulation's explicit language and plain meaning. Nor has Petitioner identified interpretive language that would grant it an exception from the regulation's reach.

Id. at 3-4. The ALJ agreed with CMS that Petitioner's argument flies in the face of the plain meaning and purpose of the regulation, citing the interpretive language in the MPIM at Chapter 4, Section 4.26.1. *Id*. at 4. Section 4.26.1 of the MPIM states, in pertinent part:

> For DMEPOS products that are supplied as refills to the original order, suppliers must contact the beneficiary prior to dispensing the refill. This shall be done to ensure that the refilled item is necessary and to confirm any changes/modifications to the order. Contact with the beneficiary or designee regarding refills shall take place no sooner than 14 calendar days prior to the delivery/shipping date. For subsequent deliveries of refills, the supplier shall deliver the DMEPOS product no sooner than 10 calendar days prior to the end of usage for the current product. This is regardless of which delivery method is utilized. DME MACs shall allow for the processing of claims for refills delivered/shipped prior to the beneficiary exhausting his/her supply.[5]

Having considered this manual provision, the ALJ concluded that:

> [t]his language puts the supplier on notice that it cannot blindly refill products without ascertaining first whether the consumer (the beneficiary) still needs the product. A beneficiary's death – which clearly obviates the need for a refill – is something that a supplier should ascertain before refilling the product. In fact, a substantial percentage of the claims that are at issue here involve refills.

Id. at 4 (citing CMS Ex. 4 at ¶ 7).

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[5] The MPIM, CMS Publication 100-08, is available at https://www.cms.gov/regulations-and-guidance/guidance/manuals/internet-only-manuals-ioms-items/cms019033.html.

In addition, the ALJ rejected Petitioner's contention that CMS had failed to prove that the beneficiaries subject of the approximately 300 rejected claims were in fact deceased. ALJ Dec. at 3. Consequently, the ALJ found that the record reflected more than enough claims submitted for items supplied to deceased beneficiaries to support revocation, reasoning that:

> [i]t is unnecessary for me to decide precisely how many claims Petitioner filed for services rendered to beneficiaries who were deceased. CMS asserts that there were more than 300 claims. Petitioner has specifically challenged CMS's assertions concerning some of these claims but has not challenged the great bulk of them. However, whether the precise number is somewhat less than 300 or a few more is irrelevant. As is made evident by the regulation the submission by Petitioner of even one claim for reimbursement for services to beneficiaries who were deceased is a sufficient basis for CMS to revoke participation and billing status. Here, there were many such claims even if the precise number is in dispute. That is sufficient to justify CMS's action. Given that, adjudicating the precise number of prohibited claims becomes a dry and useless academic exercise.

Id. at 3. The ALJ also stated that:

> although Petitioner quibbles with CMS about the exact number of deceased beneficiaries for whom it filed claims, it never denies – or even addresses – the core of CMS's case.

Id.

The ALJ rejected Petitioner's defense that what it characterizes as its billing mistakes are not a proper basis for revocation. He also found irrelevant Petitioner's argument that it actually had shipped the items for which it billed Medicare, reasoning that the items were unnecessary because the deceased have no use for DME, and therefore Medicare never should have been billed for those items. *Id*. at 5.

Finally, the ALJ rejected Petitioner's argument that CMS had advanced a new theory which was not the basis for the contractor's initial determination or for the reconsidered determination. *Id*. Petitioner argued that CMS had newly argued that Petitioner "failed to exercise an affirmative duty to assure that the beneficiaries to whom it shipped supplies were not deceased." *Id.,* citing Petitioner's Brief to the ALJ at 13-14. In addition, Petitioner asserted that this "new theory" "depart[ed] from what is required by" the MPIM. *Id*. The ALJ found that the reconsidered determination was "explicit" in following the MPIM, quoting relevant language "verbatim." *Id*. at 6. Accordingly, the ALJ also rejected Petitioner's claims that CMS had "constantly shifted the basis for revocation" and found Petitioner's claims of denial of due process unsupported. *Id.*

In its Request for Review (RR), Petitioner, in sum, contends that the ALJ erred in sustaining the reconsidered determination on summary judgment because, Petitioner argues, the ALJ failed to apply the proper legal standards, disregarded evidence demonstrating genuine issues of material fact, and incorrectly concluded that CMS proved it was entitled to summary judgment. RR at 1. Petitioner argues that the ALJ ignored evidence which Petitioner had submitted, prior to the reconsidered determination, refuting CMS's allegations. Petitioner also argued that the ALJ ignored the fact that Petitioner had disputed whether CMS had sufficiently demonstrated that the beneficiaries in question were in fact deceased, citing its pre-hearing exchange and response to CMS's Motion for Summary Judgment. *Id*. at 2. Petitioner also argues that the ALJ failed to consider its Due Process arguments and rejected without consideration Petitioner's contentions that it maintained a "robust compliance program" and its Constitutional argument against being subject to "a regulation for which it is impossible to guarantee compliance[.]" *Id*. at 4.

Standard of Review

Whether summary judgment is appropriate is a legal issue that we address de novo. *Patrick Brueggeman, D.P.M.*, DAB No. 2725, at 6 (2016); *1866ICPayday.com, L.L.C.*, DAB No. 2289, at 2 (2009), *citing Lebanon Nursing & Rehab. Ctr*., DAB No. 1918 (2004).

Summary judgment is appropriate if there is no genuine dispute of fact material to the result and the moving party is entitled to judgment as a matter of law. *See 1866ICPayday.com* at 2, *citing Celotex Corp. v. Catrett*, 477 U.S. 317, 322-25 (1986); *Everett Rehab. & Med. Ctr*., DAB No. 1628, at 3 (1997), citing *Travers v. Shalala*, 20 F.3d 993, 998 (9th Cir. 1994). The Board construes the facts in the light most favorable to the appellant and gives it the benefit of all reasonable inferences. *See Livingston Care Ctr*., DAB No. 1871, at 5 (2003), *aff'd, Livingston Care Ctr. v. U.S. Dep't of Health & Human Servs*., 388 F.3d 168, 172-73 (6th Cir. 2004).

To defeat an adequately supported summary judgment motion, the nonmoving party may not rely on the denials in its pleadings or briefs, but must furnish evidence of a dispute concerning a material fact – a fact that, if proven, would affect the outcome of the case under governing law. *Senior Rehab. & Skilled Nursing Ctr*., DAB No. 2300, at 3 (2010), *aff'd, Senior Rehab. & Skilled Nursing Ctr. v. Health & Human Servs*., 405 F. App'x 820 (5th Cir. 2010). A party "must do more than show that there is 'some metaphysical doubt as to the material facts . . . Where the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no genuine issue for trial."' *Mission Hosp. Regional Med. Ctr*., DAB No. 2459, at 5 (2012) (*quoting Matsushita Elec. Industrial Co. v. Zenith Radio, Ltd., 475 U.S. 574, at 587 (1986)), aff'd, Mission Hosp.*

Reg'l Med. Ctr. v. Sebelius, No. SACV 12-01171 AG (MLGx), 2013 WL 7219511 (C.D. Cal. 2013), *aff'd sub nom. Mission Hosp. Reg'l Med. Ctr. v. Burwell*, 819 F.3d 1112 (9th Cir. 2016). In examining the evidence to determine the appropriateness of summary judgment, an ALJ must draw all reasonable inferences in the light most favorable to the non-moving party. *See Brightview Care Ctr.*, DAB No. 2132, at 2, 9 (2007); *but see Cedar Lake Nursing Home*, DAB No. 2344, at 7 (2010); *Brightview* at 10 (entry of summary judgment upheld where inferences and views of nonmoving party are not reasonable). Drawing factual inferences in the light most favorable to the non-moving party does not require that an ALJ accept the non-moving party's legal conclusions. *Cedar Lake Nursing Home* at 7.

Our standard of review on a disputed issue of law is whether the ALJ decision is erroneous. *Guidelines – Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's or Supplier's Enrollment in the Medicare and Medicaid Programs*, http://www.hhs.gov/dab/divisions/appellate/guidelines/prosupenrolmen.html

Analysis

The administrative record supports the ALJ's entry of summary judgment for CMS because it is undisputed that Petitioner engaged in a pattern of abusive billing by supplying DMEPOS to deceased Medicare beneficiaries. In affirming the ALJ we first address the Petitioner's claim that section 424.535(a)(8) of the regulation does not apply to mail-order suppliers such as Med-Care. Next we address the ALJ's Decision granting summary judgment in favor of CMS.

I. Med-Care is subject to revocation if, as here, it is found to have violated 42 C.F.R. § 424.535(a)(8).

The ALJ did not err when he rejected Petitioner's argument that it is exempt from revocation under section 424.535(a)(8). We agree with the ALJ that Petitioner's argument not only "contradicts the regulation's plain meaning[,] but it contradicts the regulation's obvious purpose." ALJ Dec. at 4. When interpreting a regulatory provision we first look to the plain language of the regulation. The plain language of the regulation prohibits abusive billing, which includes where a supplier submits claims for services which could not have been furnished to a specific individual on the date of service because the specific individual is deceased. The regulation does not distinguish between providers and suppliers, holding both to the same standard when billing for services furnished to Medicare beneficiaries. As we will discuss below, Petitioner does not dispute that it billed Medicare for furnishing DMEPOS supplies to deceased beneficiaries.

Similarly, the regulation makes no distinction between "in-person" suppliers and "mail-order" suppliers, despite Petitioner's contentions to the contrary. Petitioner proffers no authority to support its theory that CMS intended for subsection (a)(8) of the regulation to apply only to so-called "in-person" suppliers, such as physicians and podiatrists. Moreover, Petitioner, in advancing its argument that subsection (a)(8) of the regulation contains an exception for mail-order suppliers, relies on a theory of impossibility – that it must be impossible for the supplier to furnish the item or service for the regulation to apply. However, Petitioner likewise provides no support for this argument, and we find no merit in it.

We disagree with Petitioner's position that CMS intended to distinguish mail-order suppliers from in-person suppliers. Petitioner relies on a particular passage from the preamble to the final rule where CMS addresses the prevalence of abusive billing and the need to make it a point of emphasis with its contractors. In response to an inquiry about the guidance CMS would provide contractors and the likelihood that contractors would be overburdened by the need to review voluminous claims for possible abusive billing, CMS wrote:

> We have found numerous examples of situations where a physician claims to have furnished a service to a beneficiary more than a month after their recorded death, or when the provider or supplier was out of State when the supposed services had been furnished. In these instances, the provider has billed the Medicare program for services which were not provided and has submitted Medicare claims for service to a beneficiary who could not have received the service which was billed. 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.***

73 Fed. Reg. at 36,455 (emphasis added). It is clear to us from the context that CMS, in responding to an inquiry about the impact on Medicare contractors of subsection (a)(8) of the regulation, used post-death physicians' claims as an illustration of the kind of instances of abusive billing practices Medicare contractors commonly face, thus necessitating the regulation. This view is supported by that fact that CMS ended its response by stating that this basis for revocation – billing for services furnished to deceased beneficiaries – is directed at "providers and suppliers" who engage in abusive billing practices. CMS did not qualify or tailor its conclusion to say that the regulatory provision was intended to apply only to physicians or only to "in-person" suppliers of services. The fact that CMS had found "numerous examples" of instances where physicians billed for services to deceased beneficiaries does not equate to the intent on the part of CMS to exempt other suppliers who are not physicians. The example of physician billing was illustrative but not restrictive.

Even if we found subsection (a)(8) of the regulation to be ambiguous, which we do not, CMS's interpretation is entitled to deference. It is well-settled that where the language of a statute or regulation is ambiguous, a reasonable interpretation of the text by the agency responsible for administering the provision is entitled to deference. *The Orthotic Ctr., Inc.*, DAB No. 2531, at 18-19 (2013); *Dist. Mem'l Hosp. of Southwestern N.C., Inc. v. Thompson*, 364 F.3d 513, 518 (4th Cir. 2004); *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994). Here, the ALJ found that CMS had "identified interpretive language that supports the regulation's plain meaning and purpose," citing the MPIM, Chapter 4, Section 4.26.1, which requires DMEPOS suppliers to contact a beneficiary (or designee) no sooner than 14 calendar days prior to dispensing a refill to ensure that the item is necessary and to confirm any changes or modifications to the order. *See* ALJ Dec. at 4. We agree with the ALJ that CMS has reasonably construed the regulation in invoking it for purposes of revoking Petitioner's Medicare enrollment and billing privileges. It would be unreasonable to conclude that CMS intended to create an exception under subsection (a)(8) of the regulation for mail-order suppliers, and then issue interpretive guidance on compliance with the regulation that does not specifically exempt mail-order suppliers from the regulation's reach. In light of our conclusion that CMS reasonably construed subsection (a)(8), and in view of the regulatory history showing that CMS's construction of subsection (a)(8) in this case is consistent with CMS's prior statements in the preamble to the final rule about the intent of the regulation, we defer to CMS's interpretation of subsection (a)(8) as applying to all Medicare suppliers, including mail-order DMEPOS suppliers.

II. Summary judgment was appropriate because the ALJ correctly determined that there is no genuine dispute of material fact as to whether Petitioner violated section 424.535(a)(8).

As discussed above, the ALJ noted that Petitioner never disputed the "core of CMS's case" against it for abusive billing. *See* ALJ Dec. at 3. Med-Care contends that the number of beneficiary claims being in dispute, as well as questions surrounding the sufficiency of CMS's evidence of the death of beneficiaries to whom supplies were furnished, means that summary judgment was not appropriate. *See* RR at 2-3. We find that the summary judgment motion was well-supported by evidence in the record. In addition, we find that Petitioner failed to furnish evidence of a dispute concerning a material fact and relies solely on pleadings and briefs which do not constitute evidence of a dispute of material fact.

To defeat an adequately supported summary judgment motion, the nonmoving party may not rely on the denials in its pleadings or briefs, but must furnish evidence of a dispute concerning a material fact - a fact that, if proven, would affect the outcome of the case under governing law. *Senior Rehab. & Skilled Nursing Ctr.* at 3. CMS asserts that Med-Care submitted approximately 300 prohibited claims, but Med-Care contends that CMS

was unable to establish the exact number of prohibited claims, and that this inability is fatal to summary judgment. While we do not adopt the ALJ's view that "adjudicating the precise number of prohibited claims" is a "dry and useless academic exercise," ALJ Dec. at 3, we find that undisputed material evidence in the record establishes the fact of abusive billing by Med-Care under the regulations.

Among the 20 exhibits submitted by CMS and received into the record was a spreadsheet identified as CMS Ex. 3. CMS Ex. 3 documents data for approximately 300 instances of Medicare billing by Petitioner between January 8, 2012 and May 16, 2015. Witness P.N., a Program Evaluation Officer responsible for data analysis for the Center for Program Integrity (CPI) at CMS, established through his sworn declaration that he discovered these claims through his analysis of data from the Integrated Data Repository (IDR), which includes the date of the beneficiary's death, as provided by the Social Security Administration (SSA).[6] CMS Ex. 4, at 2 ¶ 5. The data analysis was limited to:

> claims for services rendered thirty days or more after the beneficiary's date of death because of the nature of Med-Care's business model, namely, the shipping of supplies and equipment, and because of the requirement that the supplier contact the beneficiary no sooner than fourteen calendar days prior to shipping to ensure that the supplies are necessary. Thus, the data analysis would not capture those claims in which the beneficiary was alive during some part of the fourteen day contact period but died before Med-Care shipped the supplies or the supplies were delivered.

Id. at 2 ¶ 6. P.N. also stated that "eighty-five percent of the claim lines submitted" 30 days after the beneficiaries' deaths were refills. *Id*. at ¶ 7.

Petitioner argued that CMS lacked sufficient evidence to prove that the beneficiaries associated with the questioned claims were actually deceased on the dates of service. RR at 2-3. Petitioner contends that "[t]he only evidence of death put forth by CMS is print outs from a CMS system that includes a listed date of death." *Id*. Petitioner contends that it "highlighted numerous examples of the unreliability of CMS' supposed evidence of the beneficiaries dates of death . . . ." *Id*. at 3. In support of this argument, Petitioner relies on a 2014 ALJ decision, *D & G Holdings, LLC d/b/a Doctors Lab*, DAB CR3120, at 21 (2014). As we have noted on numerous occasions, ALJ decisions have no

[6] Witness P.N. stated that his analysis of the data reflected on CMS Exhibit 3 shows "more than 300 instances where Med-Care shipped medical supplies and/or equipment to beneficiaries who were deceased for at least thirty days" and "Med-Care billed Medicare for those supplies." CMS Ex. 4, at 2-3 ¶¶ 6-9. Med-Care asserted below and on appeal that "CMS' spreadsheet shows 299 unique beneficiaries, not 316[,]" the number shown in the revocation notice and the reconsidered determination. Pet. Resp. to MSJ at 15; RR at 21; CMS Exs. 1, at 1; 2, at 3. The precise number is not material, and we use "approximately 300" to refer to the number of claims submitted on behalf of unique beneficiaries shown on CMS Exhibit 3.

precedential weight and are useful only to the extent their reasoning is on point and persuasive. *John M. Shimko, D.P.M.*, DAB No. 2689 at 5 (2016). In addressing the merits, the ALJ in *D & G Holdings* stated that CMS must show in its prima facie case that more than one claim was submitted that could not have been provided as billed. The ALJ then concluded that CMS had not provided sufficient evidence to show that the regulation was violated. *D & G Holdings* at 21. In *D & G Holdings*, the ALJ found that "Petitioner's pleadings are extremely persuasive that [the Medicare contractors] 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." *Id*. at 23. The ALJ reasoned that CMS failed to make a *prima facie* case that abusive billing had occurred and that the kind of billing errors evident in the record in that case were indicative of the kind of isolated occurrences and accidents for which the revocation authority was not intended. *See id.* at 18, 23-24.

We find nothing in the record or in the ALJ decision to support Petitioner's position here. Even if Petitioner has highlighted examples of the unreliability of CMS's evidence, Petitioner has failed to demonstrate through its own affirmative evidence that CMS erred in determining the dates of death in all of the questioned claims. Even if Petitioner could prove that some of the dates of death were calculated incorrectly, it still would not foreclose the conclusion, which we have reached here, that enough of the improper claims in the record were for services to beneficiaries whose dates of death were correct. We note that Petitioner also relies on a GAO report from May of 2013 titled "Preliminary Observations on the Death Master File" to support its argument that the date of death information CMS obtains from SSA is unreliable. Pet. Ex. 7. However, the GAO report does not refute evidence in the record of at least three claims by Med-Care for services supplied to deceased beneficiaries.

In its motion for summary judgment, CMS noted that, on reconsideration, "Med-Care admitted that it had submitted 78 claims for beneficiaries it knew were deceased, citing 'clerical error' as the reason." MSJ at 3, citing CMS Ex. 2 (the reconsidered determination dated December 15, 2015). Med-Care's December 8, 2015 appeal of the notice of revocation has not been made part of the record before the Board. However, in its reconsidered determination, CMS summarized the items it considered for that review:

> **SUMMARY OF SUBMITTED DOCUMENTATION:**
>
> - December 8, 2015 Med-Care Diabetic and Medical Supplies, Inc. (Med-Care) Appeal
> - Appointment of Representative form (Tab A)
> - CMS's initial determination letter dated November 12, 2015, revoking Med-Care's billing privileges (Tab B)
> - Copy of Med-Care's Compliance Program, revised & effective September 14, 2014 (Tab C)

- Example of current refill ticket completed by Med-Care representatives when communicating with Medicare beneficiaries prior to providing refills (Tab D)
- Patient File Maintenance
  - Showing Medicare eligible check indicated the beneficiary was alive and that Med-Care received confirmation to ship supplier (Tab E)
  - Showing Med-Care erred in not documenting eligibility information prior to making contact regarding a refill, clerical error (Tab F)
  - Showing the beneficiary was alive at the date of service (Tab G)
  - Showing administrative errors caused the wrong date to be keyed in for a claim (Tab H)
  - Showing the beneficiary passed away after a request for supplier, but before delivery (Tab I)

CMS Ex. 2, at 2. Based on these documents, CMS calculated that, among the 316 claims identified by CPI, Med-Care attributed 78 errant claims to clerical error, presumably as illustrated in the examples above identified at Tabs H and I. *Id*. at 3. Given the opportunity to submit its December 8, 2015 appeal along with other evidence in support of its request for hearing, Med-Care failed to do so. Accordingly, the record only reflects CMS's conclusion that Med-Care attributed 78 errant claims to clerical error. Med-Care contends that it has disputed this conclusion both in its Request for Hearing as well as in its opposition to summary judgment, however, it offers no evidence that those 78 claims were for services furnished to living Medicare beneficiaries.

In its Request for Hearing, Petitioner addresses the issue of whether it asserted clerical error as the basis for submitting claims for services furnished to the deceased thusly:

> In its reconsideration request, Petitioner indicated ***that some claims associated with the beneficiaries and items identified by CMS were submitted due to administrative clerical errors***.

RFH at 11 (emphasis added). Here, given the opportunity to challenge CMS's reconsidered determination, Petitioner instead agreed that "some claims . . . were submitted due to administrative clerical errors." *Id.* Moreover, rather than explain how CMS erred in determining on reconsideration that Petitioner had filed improper claims, Petitioner argued merely that its improper claims resulting from administrative errors were virtually impossible to avoid, stating:

> As discussed throughout this hearing request, the claims identified as the basis for this revocation are for DME items, primarily diabetic supplies, not services such as those at issue in the cases cited above. As a mail order supplier, the majority of Petitioner's business is conducted via computer systems and data entry, tracking hundreds of thousands of patients throughout the country that order and receive a broad range of items. During the time period encompassed by CMS's list, Petitioner submitted millions of claims. It is patently absurd to expect that a supplier submitting such a large quantity of claims will never make an accidental billing error. CMS's own preamble to the "abuse of billing" regulation made clear that "***this revocation authority is not intended to be used for isolated occurrences or accidental billing errors***." 73 Fed. Reg. 36448, 36455 (June 27, 2008) (emphasis added).

Id. Rather than deny that it submitted 78 claims for services furnished to deceased beneficiaries, Petitioner implied that its billing in those instances was accidental, and that therefore, the regulation was not intended to apply to those claims.

In its Pre-Hearing Exchange and Response to CMS's Motion for Summary Judgment (Pet. Resp. to MSJ), Petitioner denies conceding that it submitted the aforementioned 78 claims as a result of administrative error. In a paragraph titled "There Were Not 78 Clerical Errors" Petitioner, relying on the above-cited passage from its Request for Hearing, contends that:

> [T]he evidence in this case demonstrates that such statement is inaccurate. [Citation omitted.] CMS has submitted no evidence identifying these supposed 78 claims. They did not and they cannot. Med-Care complied with Medicare requirements and the evidence demonstrates that the company shipped supplies in good faith believing that the beneficiary was alive. CMS has failed to present evidence on a disputed fact and cannot carry its burden of making a prima facie showing.

Id. at 19. Petitioner's bare denial in its brief is not enough to create a dispute of material fact for purposes of overcoming a summary judgment motion. Petitioner could have submitted its December 8, 2015 request for reconsideration to challenge CMS's conclusion (if, in fact, the request for reconsideration showed that Petitioner had *not submitted* 78 errant claims) but Petitioner did not. Moreover, Petitioner's contention here is inconsistent with its position in its Request for Hearing. The record includes the reconsidered determination, citing the 78 claims attributed by Petitioner to administrative error, and Petitioner's admission in the Request for Hearing; the record does not contain any proof submitted by Petitioner that it did not submit the 78 improper claims.

Even if Petitioner could successfully challenge through competent evidence CMS's conclusion that Petitioner conceded that it had submitted 78 claims for services furnished to deceased beneficiaries, CMS has provided evidence of 14 specific instances of such claims which Petitioner fails to rebut. CMS Ex. 6 is the sworn declaration of witness K.L. K.L. is a business analyst with CGS Administrators, LLC (CGS), the Medicare Administrative Contractor for Jurisdiction C, which processes Med-Care's billing claims. K.L. explains that the documents contained in CMS Exhibit 5 are screen shots from the Medicare Common Working File, which contains date of death information from SSA. CMS Ex. 6, at 1-2 ¶ 4. In addition, she explains that CMS Exs. 7-20 "contain screen prints for fourteen (14) Medicare beneficiaries[,]" along with annotations K.L. supplied documenting the services furnished, the claims submitted by Med-Care and the dates of service. *Id*. at 2 ¶ 5. She next describes each transaction in detail. *See id*. at 3-9.

Review of Petitioner's exhibits reveals no evidence to refute that the beneficiaries listed in CMS Exhibits 3, 6, and 7-20 were all identified as deceased at least one month, and as many as 15 months, before Petitioner noted in its own database "OK TO SHIP." Petitioner's Exs. 4 and 6 show screen shots of a "Patient File Maintenance" program. The screen depicted in these exhibits consists of numerous fields for data entry, including fields labeled "Patient ID," "Name," Patient Status," and "Date of Death," among others. *Id*. The large majority reflects approval to send supplies to a beneficiary noted on the screen as deceased on a certain date.[7] For example, Pet. Ex. 6 reflects an order for beneficiary O.B., who is noted deceased as of March 17, 2012, but with the accompanying notation "Patient has nearly exhausted all supplies, OK TO SHIP" on June 4, 2012, nearly three months later. Pet. Ex. 6, at 3. Such entries occur for each beneficiary listed in the 378 pages of Petitioner's Exhibit 4 and in the 76 pages of its Exhibit 6. In each instance, the beneficiary's date of death is listed and a note below indicates that Petitioner will furnish supplies.

Petitioner is correct that the preamble to the final rule explains that the regulation is not intended to apply to accidents and isolated incidents. However, CMS was clear that the regulation would apply to a pattern of prohibited claims, which consists, at a minimum, of three prohibited claims. *See* 73 Fed. Reg. at 36,455. Accordingly, CMS need only provide evidence of three or more instances of billing by Med-Care for items furnished to deceased beneficiaries to be entitled to summary judgment. By contrast, Med-Care must furnish evidence disputing the existence of a pattern of abusive billing in order to overcome summary judgment. In short, Petitioner must furnish evidence disputing CMS's prima facie case of a pattern of abusive billing.

[7] Not every page of these exhibits is completely legible due to degeneration of the image, presumably upon being photocopied. However, the vast majority of the pages in these exhibits are legible.

Having reviewed the entire record, we are unable to locate any evidence furnished by Petitioner which creates a dispute of material fact that Petitioner billed Medicare for services furnished to deceased beneficiaries at least 14 times, based upon CMS Exhibits 7 – 20. The ALJ found that there were "many more" than the three instances of claims for services to deceased beneficiaries required to establish a pattern of abusive billing. ALJ Dec. at 5. We conclude that the record supports the conclusion and Petitioner has put forth no evidence to the contrary. Therefore, we find that summary judgment was proper.

III. Petitioner's other arguments lack merit

In its request for review, Med-Care contends that the ALJ dismissed "Med-Care's due process arguments, namely, the lack of notice of the specific claims at issue and the deprivation of a reasonable opportunity for Med-Care to defend against these claims." RR at 4. Specifically, Med-Care argues that the ALJ failed to consider that its procedural due process rights were violated when the CMS hearing officer "inexplicably relied" upon "allegations or evidence regarding an alleged 2,510 claim submissions" of which "Med-Care received no notice . . . as the basis for upholding the revocation." RR at 8. In its reconsidered decision, CMS cited "2,510 claim lines where Med-Care submitted multiple dates of service for a beneficiary that [was] already dead at the time the service took place" and did not simply rely on the 316 instances cited by CMS in its notice of revocation. *See* CMS Ex. 2, at 2. We agree with the ALJ's rejection of this argument, where he concluded that–

> [t]he reconsideration determination in this case clearly recites CMS's basis for revocation of Petitioner's Medicare participation and billing privileges, and CMS has made no argument that goes beyond the four corners of that document. Petitioner has not satisfied me that CMS failed to provide it with notice of its action.

ALJ Dec. at 6. Even if Petitioner first learned at the reconsideration stage that CMS had reviewed *2,510 claim lines*,[8] that, in and of itself, does not constitute a violation of due process. The Board has held, most recently in *Access Footcare, Inc. and Robert Metnick D.P.M.,* DAB No. 2752 (2016), that "CMS can cure notice deficiencies during subsequent ALJ proceedings." *Access Foot Care* at 13, citing *Green Hills Enters., LLC*,

[8] CMS witness P.N. explained the difference between a claim and a claim line in his sworn declaration: "A Medicare claim can contain multiple claim lines. Each claim line refers to a specific Healthcare Common Procedure Coding System (HCPCS) code. Each HCPCS code refers to a different supply or piece of equipment. Thus, the number of claims reflected on the spreadsheet provided to Med-Care in support of the revocation ("spreadsheet") is fewer than the number of claim lines because claims can contain more than one claim line." CMS Ex. 4, at 3 ¶9. Petitioner did not dispute this explanation.

DAB No. 2199, at 8 (2008); *Fady Fayad, M.D.*, DAB No. 2266, at 10-11 (2009), *aff'd*, *Fayad v. Sebelius*, 803 F. Supp. 2d 699 (E.D. Mich. 2011). Moreover, the Board noted that "even assuming inadequate notice, it will not find a due process violation absent a showing of resulting prejudice." *Green Hills Enters.* at 8, citing *Livingston Care Ctr.* at 20; *see also Dinesh Patel, M.D.*, DAB No. 2551, at 8 (2013) (finding that there was no prejudice resulting from alleged inadequate notice where Petitioner did not "claim that the alleged notice deficiency impaired his ability to defend himself before either the ALJ or the Board.").

Here, CMS noted in its reconsidered determination that "[f]rom the time period of January 1, 2012 to December 30, 2014 CMS identified 2,510 claim lines where Med-Care submitted multiple dates of service for a beneficiary that [was] already dead at the time the service took place." CMS Ex. 2, at 2. We do not view this reference by CMS to the number of *claim lines* which were subject of the review of its analysts as an attempt to increase the number of improper claims it alleges were the basis for revocation. Rather, we view this as the context for the analysis which resulted in CMS taking action to revoke Petitioner based upon approximately 300 improper claims out of the 2,510 claim lines it analyzed. Throughout the pendency of this revocation action, CMS has predicated revocation on the approximately 300 improper claims identified in the revocation notice and CMS never expanded its basis for revocation to include additional claims. The reconsidered determination did not change this. In fact, before the ALJ, CMS *reduced*, rather than increased, the number of improper claims it alleged were the basis for revocation. *See* MSJ at 5 n.5. Accordingly, we find no support in the record for Petitioner's contention that CMS changed the basis of revocation without proper notice, or that Petitioner suffered any prejudice as a result of CMS discussing the extent of its review in the reconsidered determination.

Similarly, we find no merit in Petitioner's complaint that a contractor, and not CMS, first issued the revocation letter. CMS withdrew that letter and reissued it through CPI. Petitioner complains that it did not receive CMS Ex. 3 with the re-issued revocation notice, although the spreadsheet was attached to the original revocation. Yet, Petitioner makes no showing of prejudice as a result of receiving the spreadsheet with the first revocation letter but not with the second.

Petitioner argues throughout this appeal that it never received payment for any of the claims at issue and that therefore it did not engage in abuse of its billing privileges. This ignores the fact that the regulation prohibits abusive *billing*, and is not predicated upon the supplier receiving actual payment.

Petitioner contends that the ALJ failed to consider whether there was good cause to receive Med-Care's evidence submitted for the first time at the ALJ level, and claims that the ALJ did not consider the evidence. RR at 3. However, although the ALJ did not rule expressly on whether good cause existed for him to admit Petitioner's evidentiary exhibits, the ALJ nonetheless admitted Petitioner's exhibits into the record. ALJ Dec. at 1. Having reviewed the ALJ's summary judgment decision *de novo*, we find that Petitioner has not been prejudiced by the lack of an express ruling by the ALJ, where its exhibits have been made part of the record below. The ALJ explained why he saw no need to rule on whether good cause existed to admit Petitioner's evidence into the record, noting that "there is no dispute about the nature of Petitioner's conduct, even if the parties dispute the precise extent of it." *Id*. at 2. The fact that the ALJ was not persuaded by Petitioner's evidence does not equate to the ALJ not considering it.

Petitioner contends that the ALJ ignored evidence of the strength and effectiveness of its compliance policies. *See* RR at 4. However, Petitioner failed to show how its compliance policies refute CMS's evidence of Petitioner's abusive billing. We note that a rigorous and usually effective compliance program is not mutually exclusive of a pattern of abusive billing. In fact, Petitioner complains that the compliance standard is too high if suppliers such as Petitioner can maintain a strict compliance policy and still face revocation for billing errors committed in a fraction of its claims. *See* RR at 5, 29-30. This, however, is a policy question for which the Board is not the proper forum.

Conclusion

For the reasons set out above, the Board affirms the ALJ Decision upholding the revocation of Petitioner's Medicare enrollment and billing privileges for a period of three years.

/s/
Constance B. Tobias

/s/
Susan S. Yim

/s/
Christopher S. Randolph
Presiding Board Member