Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Arriva Medical, LLC,
(NPI: 1023285723,
Supplier No.: 6175500001),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-17-233

Decision No. CR4834

Date: April 25, 2017

DECISION

Arriva Medical, LLC (Petitioner or "Arriva"), is a supplier of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). Petitioner participated in the Medicare program until the Centers for Medicare & Medicaid Services (CMS) revoked its Medicare supplier number and billing privileges and established a three-year re-enrollment bar based on noncompliance with 42 C.F.R. § 424.535(a)(8)(i) because it shipped diabetic supplies to Medicare beneficiaries who were deceased at the time of service and billed Medicare for those supplies. Petitioner appeals the revocation of its Medicare supplier number. For the reasons detailed below, I find that Petitioner was not compliant with Medicare requirements and that CMS properly revoked its supplier number.

I. Background

According to Petitioner, it is "by far the largest supplier of home-delivered diabetic testing supplies in the nation."[1] Petitioner Brief (P. Br.) at 3. Petitioner states that its "services currently support more than half of the total services furnished under the National Mail-Order Program, serving over 500,000 Medicare beneficiaries." P. Br. at 3; *see, e.g.*, 42 U.S.C. § 1395w-3. According to Petitioner, its "patient base is generally elderly and infirmed, with many beneficiaries located in rural areas with limited ability to travel." Petitioner Exhibit (P. Ex.) 3 at 3. Petitioner "serves its Medicare beneficiary patient base only through mail-order services, and does not have any face-to-face contact with Medicare beneficiary patients." P. Ex. 3 at 3.

In a letter dated October 5, 2016, CMS's Provider Enrollment and Oversight Group notified Petitioner that its Medicare supplier number would be revoked for a period of at least three years, effective November 4, 2016. CMS stated that the basis for revocation was noncompliance with 42 C.F.R. § 424.535(a)(8)(i) (Abuse of Billing Privileges). CMS Exhibit (Ex.) 1 at 1. CMS explained the following, in pertinent part:

> Data analysis conducted on claims billed by Arriva Medical, LLC, for dates of service between April 15, 2011 and April 25, 2016, revealed that Arriva Medical, LLC billed for items/services provided to 211 Medicare beneficiaries who, per the Social Security Administration Death Master File, were deceased on each purported date of service.

CMS Ex. 1 at 1. CMS enclosed a "sample of the claims data" as Enclosure A to the letter. CMS Ex. 1 at 1. Enclosure A to the initial determination is a list of 47 claims, to include identifying information about each beneficiary and the claim control number, in which the date of service followed a beneficiary's date of death. CMS Ex. 1 at 3-4.

Petitioner, through its current counsel, submitted a request for reconsideration (Reconsideration Request) on October 28, 2016, in which it addressed the 47 claims identified by CMS in its October 5, 2016 letter.[2] Petitioner explained that, with respect to

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[1] A DMEPOS supplier is an "entity or individual, including a physician or Part A provider, which sells or rents Part B covered items to Medicare beneficiaries and which meets the standards" set forth in 42 C.F.R. § 424.57. 42 C.F.R. § 424.57(a).

[2] Petitioner submitted a copy of its request for reconsideration as Exhibit D to its request for hearing. While both parties cite to the request for reconsideration in their briefs, neither party submitted the complete request for reconsideration as a supporting exhibit. I will cite to the portions of the request for reconsideration that are exclusively found in Exhibit D to the request for hearing, which is not consecutively paginated, using the page numbers of the .pdf document. For purposes of clarity, I refer to Exhibit D to the request

deceased beneficiaries that CMS identified had been shipped diabetic supplies after their deaths, it has "documented evidence that the Medicare beneficiary, or another individual acting on the Medicare beneficiary's behalf (i.e., a caregiver for the beneficiary), specifically requested a refill of diabetic testing supplies from Arriva." Reconsideration Request at 5. Petitioner explained that each order had been authorized and stated that "in most cases" orders are "supported by contemporaneous notes of the call, transcripts of a telephone call with Arriva's Interactive Voice Response system known as 'ELIZA', or a completed reorder card sent to Arriva in the mail." Reconsideration Request at 5. Petitioner explained that in each of the instances in which it provided an item to a deceased beneficiary, it "received a valid request for a refill of diabetic testing supplies for a Medicare beneficiary and furnished supplies pursuant to that request." Reconsideration Request at 5.

Petitioner did not deny that it provided items to deceased beneficiaries, but argued that its limited access to the HIPAA Eligibility Transaction System (HETS) (which it explained contains information regarding a beneficiary's status, to include death), was the reason it was unaware of the death of numerous beneficiaries. Reconsideration Request at 5-7. However, Petitioner admitted that there were a number of instances in which HETS reported a beneficiary's death, but Petitioner shipped diabetic supplies anyway. Petitioner explained, in a footnote, that on nine occasions it had shipped supplies to beneficiaries that had already been reported by HETS as being deceased, stating:

> Arriva acknowledges that there are 9 claims in the sample where a Medicare eligibility check run prior to the date a caregiver for the beneficiary ordered supplies returned a status code that the beneficiary was deceased, yet Arriva failed to identify the consumer's fraud[3] and

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for hearing as "Reconsideration Request."

[3] While Petitioner alleged "consumer's fraud" on the part of the individuals who authorized the reorder of diabetes supplies, it has not submitted evidence showing any "consumer's fraud." I do accept, for purposes of summary judgment, that Petitioner's recordkeeping is accurate and that none of the "patient[s]/caregiver[s]" Petitioner contacted were authorized to reorder supplies for a deceased beneficiary. Petitioner's records do not document the name of any of the individuals who approved the reorder of supplies, but rather, generally indicate that a "patient/caregiver" approved the reorder. Further, Petitioner has not submitted a copy of the script used by its automated reorder system; therefore, the evidence does not establish whether the automated telephone call from Arriva (i.e., a "robo call") clearly identified the beneficiary for whom authorization to order supplies was being sought. Petitioner has also not provided evidence showing how its automated system confirmed that the individual approving the reorder of supplies was a designee who was authorized to do so, nor do Petitioner's records list the names of individuals designated by a beneficiary to act on the beneficiary's behalf. While

> mistakenly continued to process the order. These isolated instances, which all occurred prior to February 2015, were the result of internal systems limitations that, for a short period of time during a systems change, relied on Arriva personnel to manually update Arriva's billing systems with beneficiary status information.

Reconsideration Request at 7 n.4. Petitioner included nearly 300 pages of exhibits in support of its request for reconsideration, to include a table that provided a written explanation for each of the 47 claims listed in the enclosure to the revocation letter (Exhibit 3 to Reconsideration Request; Reconsideration Request at 20-30) and copies of its records pertaining to each of the 47 claims (Exhibit 4 to Reconsideration Request[4]; Reconsideration Request at 32-300).

Petitioner stated that it "failed to identify consumer's fraud," it has acknowledged that its practice was to contact beneficiaries in order to obtain approval of a reorder of supplies, and it did not require beneficiaries (or caregivers) to initiate the reorder request. P. Ex. 3 at 4-5 ("Because Arriva is required to contact patients to confirm their need for supply re-orders, Arriva needed to ensure that Medicare beneficiaries were eligible before the contact was made, even if the beneficiary could not be reached for several days to confirm."). For example, despite the fact Petitioner had already been denied Medicare reimbursement for at least six claims based on the death of the beneficiary at the time of service (Beatrice, James, Marin, Douglas, Richard, and Elmer), Petitioner's records indicate that it initiated two telephone calls to Clarence on August 6, 2014, in order to obtain approval for a reorder of Clarence's diabetes supplies, even though Clarence had died more than a month earlier on July 3, 2014, and it knew that Clarence had already died. Reconsideration Request at 21-22; P. Ex. 4 at 1143-1145. Petitioner's records indicate that "Patient/caregiver" approved the reorder, but it is obvious that the deceased patient, himself, did not approve the reorder. P. Ex. 4 at 1143. On or about September 18, 2014, an individual who received the supplies shipped them back to Petitioner, which is inconsistent with any "consumer's fraud." P. Ex. 4 at 1145. While the individuals who authorized these refills may have erred in doing so, Petitioner has not established that any of these individuals did so for an improper reason. *See Abdul Razzaque Ahmed, M.D.*, DAB No. 2261 at 8-9 (2009), *aff'd, Ahmed v. Sebelius*, 710 F. Supp. 2d 167 (D. Mass. 2010) (stating that under the common law, "fraud generally requires a false statement or misrepresentation of material fact that the defendant makes with knowledge of its falsity and with the intent or purpose that it induce action or forbearance by another").

[4] Petitioner has included many of the same documents from Exhibit 4 to the Reconsideration Request in its submission of P. Ex. 4, at pages 1048-1051 (Douglas), 1053-1056 (Richard), 1058-1061 (Marjorie), 1063-1065 (Elmer), 1097-1100 (James), 1134-1137 (Mae), 1143-1146 (Clarence), 1148-1151 (Marin), 1163-1166 (Beatrice). While CMS observed differences between the records contained in Exhibit 4 to the Reconsideration Request and P. Ex. 4, it appears that the records pertaining to these nine

The records Petitioner submitted with its request for reconsideration confirm that over an 11-month period, from September 17, 2013 through August 19, 2014, Petitioner shipped supplies to the nine beneficiaries that it knew were deceased at the time of service. A summary of Petitioner's records regarding each of these nine claims is provided below, in chronological order:

Beatrice:

> A caregiver for the beneficiary ordered supplies[5] from Arriva on 9/7/13 through Arriva's IVR system (transcript provided). Arriva shipped the supplies to the beneficiary on 9/17/13. Arriva ran an eligibility check on the beneficiary on 9/1/13 which showed the beneficiary was deceased, however, Arriva was delayed in manually updating its order/claims processing systems to reflect the beneficiary's status. The beneficiary's date of death was 8/9/13. Arriva's claim to Medicare was denied (CO-13).

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claims are substantively identical. *See* CMS Reply Brief (Reply) at 3 n.3. Because Exhibit 4 to the Reconsideration Request lacks pagination, I will exclusively refer to the same documents as they have been filed in P. Ex. 4. Further, for ease of reference and to avoid identifying beneficiaries by full name and other identifying information, I have referred to the nine beneficiaries by their first names. I intend no disrespect to any these individuals by referring to them by only their first names, but rather, I have done so in an effort to maintain privacy for the deceased individuals and their family members.

[5] Like most of these nine cases, while Petitioner states that a caregiver "ordered" supplies, Petitioner's contemporaneous records document that a "[p]atient/caregiver" approved a reorder of supplies. The records do not establish how Petitioner confirmed that the individual authorizing the reorder was, in fact, a caregiver. Further, the records do not indicate that the "[p]atient/caregiver" *ordered* any supplies, but rather, state that the "[p]atient/caregiver" *approved* a reorder of supplies, which does not linguistically equate with *ordering* supplies. This distinction is important, in that a caregiver calling Petitioner seeking to order supplies for a deceased beneficiary is materially different, with respect to the potential for abusive billing, from a caregiver accepting a telephonic offer to refill supplies. For instance, the recipient of a phone call may receive telephone calls for numerous beneficiaries or may have limited English proficiency, and may unwittingly authorize a reorder for a deceased beneficiary. I note that in at least two of the nine claims, the recipients of the supplies contacted Petitioner to report that it had shipped supplies to deceased beneficiaries. P. Ex. 4 at 1063-1064; 1143-1145.

Reconsideration Request at 21. Petitioner's records indicate that a "Patient/caregiver approved reorder . . . ." P. Ex. 4 at 1163. National Government Services (NGS) denied the claim in December 2013 because the "date of death precedes the date of service." P. Ex. 4 at 1166.

James:

> A caregiver for the beneficiary ordered supplies from Arriva on 9/20/13 through Arriva's IVR system (transcript provided). Arriva shipped the supplies to the beneficiary on 10/4/13. Arriva ran an eligibility check on the beneficiary on 9/1/13 which showed the beneficiary was deceased, however, Arriva was delayed in manually updating its order/claims processing systems to reflect the beneficiary's status. The beneficiary's date of death was 7/8/13. Arriva's claim to Medicare was denied (CO-13).

Reconsideration Request at 25. Petitioner's records indicate that a "Patient/caregiver approved reorder . . . ." P. Ex. 4 at 1097. NGS denied the claim in December 2013 because the "date of death precedes the date of service." P. Ex. 4 at 1100.

Marin:

> A caregiver for the beneficiary ordered supplies from Arriva on 4/9/14 through Arriva's IVR system (transcript provided). Arriva shipped the supplies to the beneficiary on 4/23/14. Arriva ran an eligibility check on the beneficiary on 4/1/14 which showed the beneficiary was deceased, however, Arriva was delayed in manually updating its order/claims processing systems to reflect the beneficiary's status. The beneficiary's date of death was 3/19/14. Arriva's claim to Medicare was denied (CO-13).

Reconsideration Request at 29. Petitioner's records indicate that a "Patient/caregiver approved reorder . . . ." P. Ex. 4 at 1148. NHIC Corp. denied the claim in December 2013 because the "date of death precedes the date of service." P. Ex. 4 at 1151.

Douglas:

> A caregiver for the beneficiary ordered supplies from Arriva on 4/17/14 through Arriva's IVR system (transcript provided). Arriva shipped the supplies to the beneficiary on 4/30/14. Arriva ran an eligibility check on the beneficiary on 4/2/14 which showed the beneficiary was deceased,

> however, Arriva was delayed in manually updating its order/claims processing systems to reflect the beneficiary's status. The beneficiary's date of death was 3/15/14. Arriva's claim to Medicare was denied (CO-13).

Reconsideration Request at 22. Petitioner's records indicate that a "Patient/caregiver approved reorder, confirmed shipment of TEST STRIPS, LANCETS, CONTROL SOLUTION, BATTERIES, AND LANCING DEVICE." P. Ex. 4 at 1048. NHIC denied the claim in June 2014 because the "date of death precedes the date of service." P. Ex. 4 at 1050.

Richard:

> A caregiver for the beneficiary ordered supplies from Arriva on 5/14/14 through Arriva's IVR system (transcript provided). Arriva shipped the supplies to the beneficiary on 5/27/14. Arriva ran an eligibility check on the beneficiary on 5/1/14 which showed the beneficiary was deceased, however, Arriva was delayed in manually updating its order/claims processing systems to reflect the beneficiary's status. The beneficiary's date of death was 4/2/14. Arriva's claim to Medicare was denied (CO-13).

Reconsideration Request at 30. Petitioner's records indicate that a "Patient/caregiver approved reorder . . . ." P. Ex. 4 at 1053. NHIC denied the claim in June 2014 because the "date of death precedes the date of service." P. Ex. 4 at 1056.

Elmer:

> A caregiver for the beneficiary ordered supplies from Arriva on 6/10/14 during a live telephone call with [an] Arriva representative (contemporaneous notes of call provided). Arriva shipped supplies to the beneficiary on 6/20/14. Arriva ran an eligibility check on the beneficiary on 6/2/14 which showed the beneficiary was deceased, however, Arriva was delayed in manually updating its order/claims processing systems to reflect the beneficiary's status. The beneficiary's date of death was 3/14/14. Arriva's claim to Medicare was denied (CO-13).

Reconsideration Request at 23. Petitioner's records indicate that a "Caregiver approved reorder . . . ." P. Ex. 4 at 1063. While someone authorized the reorder on behalf of Petitioner in a live telephone call, the individual who received the shipment returned it to Petitioner. Reconsideration Request at 23; *see* P. Ex. 4 at 1064 (stating "[Caregiver] MARY ANN CI TO INFORM PT REC[EIVED] A BOX OF SUPP[LIES] BUT

WOULD LIKE TO RETURN PT IS DECEASED AS OF 3/24/2014") (capitalization in original). NGS denied the claim in July 2014 because the "date of death precedes the date of service." P. Ex. 4 at 1065.

Marjorie:

> A caregiver for the beneficiary ordered supplies from Arriva on 7/10/14 through Arriva's IVR system (transcript provided). Arriva shipped the supplies to the beneficiary on 7/23/14. Arriva ran an eligibility check on the beneficiary on 7/2/14 which showed the beneficiary was deceased, however, Arriva was delayed in manually updating its order/claims processing systems to reflect the beneficiary's status. The beneficiary's date of death was 6/14/14. Arriva's claim to Medicare was denied (CO-13).

Reconsideration Request at 27. Petitioner's records indicate that a "Patient/caregiver approved reorder . . . ." P. Ex. 4 at 1058. NHIC denied the claim in August 2014 because the "date of death precedes the date of service." P. Ex. 4 at 1061.

Clarence:

> A caregiver for the beneficiary ordered supplies from Arriva on 8/6/14 through Arriva's IVR system (transcript provided). Arriva shipped the supplies to the beneficiary on 8/19/14. Arriva ran an eligibility check on the beneficiary on 8/1/14 which showed the beneficiary was deceased, however, Arriva was delayed in manually updating its order/claims processing systems to reflect the beneficiary's status. The beneficiary's date of death was 7/3/14. Arriva's claim to Medicare was denied (CO-13).

Reconsideration Request at 21-22. Petitioner's records indicate that a "Patient/caregiver approved reorder, confirmed shipment of TEST STRIPS, LANCETS, CONTROL SOLUTION." P. Ex. 4 at 1143 (capitalization in original). The log of the automated telephone calls indicates that Petitioner attempted to call Clarence twice on August 6, 2014; the first call, at 4:31 pm, was unsuccessful because Petitioner reached a "MSG_MACHINE." Petitioner called again at 8:34 pm, at which time it reached a "Patient/caregiver" who completed the automated menu. P. Ex. 4 at 1144. While someone authorized the reorder on behalf of Petitioner, the individual who received the shipment returned it to Petitioner, as Petitioner's records indicate: "RETURNS, RECEIVED PACKING LIST FOR 8/19/14 DOS, SUPPLIES RETURNED. PER MCARE ELIGIBILITY PT IS DECEASED DOD IS 7/03/14 . . . ." P. Ex. 4 at 1145 (capitalization in original). NHIC denied the claim in September 2014 because the "date of death precedes the date of service." P. Ex. 4 at 1146.

Mae:

> A caregiver for the beneficiary ordered supplies from Arriva on 8/6/14 through Arriva's IVR system (transcript provided). Arriva shipped the supplies to the beneficiary on 8/20/14. Arriva ran an eligibility check on the beneficiary on 7/1/14 which showed the beneficiary was deceased, however, Arriva was delayed in manually updating its order/claims processing systems to reflect the beneficiary's status. The beneficiary's date of death was 6/5/14. Arriva's claim to Medicare was denied (CO-13).

Reconsideration Request at 28. Petitioner's records indicate that a "Patient/caregiver approved reorder . . . ." P. Ex. 4 at 1134. NGS denied the claim in September 2014 because the "date of death precedes the date of service." P. Ex. 4 at 1137.

On November 2, 2016, CMS issued a reconsidered determination upholding the revocation because Petitioner "billed for claims for deceased beneficiaries multiple times between April 15, 2011 and April 25, 2016." CMS Ex. 2 at 4. CMS discussed that Petitioner had conceded that it sent supplies to beneficiaries it knew were deceased, stating:

> Arriva admits that there are nine claims in the sample data where it ran a Medicare eligibility check prior to when a beneficiary ordered supplies, and found that the beneficiary was deceased but still continued to process the order. Arriva admits that there was a delay between when a beneficiary's status changed and when Arriva's internal systems were updated. However, negligent submission of multiple erroneous claims for services that could not have been delivered to beneficiaries amounts to abuse.

CMS Ex. 2 at 3. CMS, in addressing Petitioner's arguments in its request for reconsideration, further explained:

> It is irrelevant that Arriva did not receive payment from CMS for many of these claims or that it returned payments once it realized that the beneficiary was deceased. CMS has the authority to revoke a supplier in accordance with 42 C.F.R. § 424.535(a)(8)(i) when a supplier submits claims for services that could not have been furnished to a specific individual because the individual is deceased. Therefore, CMS did not err in revoking Arriva's Medicare billing privileges, pursuant to 42 C.F.R. § 424.535(a)(8).

CMS Ex. 2 at 3-4. CMS determined there was "no error in the initial determination to revoke Arriva's Medicare billing privileges for abuse of billing under 42 C.F.R.

§ 424.535(a)(8)(i)" and that "the reconsideration is denied and the revocation is upheld."[6] CMS Ex. 2 at 4.

Petitioner timely filed a request for a hearing before an administrative law judge (ALJ) on December 27, 2016.[7] On January 4, 2017, the Civil Remedies Division assigned the case to me for hearing and I issued an Acknowledgement and Pre-Hearing Order (Order). CMS submitted a brief and motion for summary judgment (CMS Br.), along with 11 proposed exhibits. Petitioner submitted a brief (P. Br.) and eight proposed exhibits. After I granted CMS's motion for leave to file a reply brief, CMS submitted a reply brief and Petitioner submitted a sur-reply brief (P. Sur-reply).

In my January 4, 2017 Order, I explained that "[a] party must exchange as a proposed exhibit the complete, written direct testimony of any proposed witness." Order, § 8. I further explained that a party has the right to cross-examine any witness for whom direct testimony has been offered. Order, § 9. In compliance with my Order, CMS submitted the written direct testimony of Patrick Neubert, David Holt, and Lisa Mathias, who are employees of CMS or its contractors, and whose testimony involved data and records submitted by CMS. CMS Exs. 7, 10, and 11. Petitioner requested an opportunity to cross-examine these three witnesses. P. Br. at 29. As I do not rely on CMS's data and records in reaching my decision, and I rely solely on Petitioner's statements and records regarding the nine claims at issue in granting CMS's motion for summary judgment, cross-examination of CMS's witnesses is unnecessary.

Petitioner submitted the written direct testimony of Brant Reamer, a vice president of Arriva (P. Ex. 3); Miguel Martinez, Arriva's director of information technology (P. Ex. 5); and James Roosevelt, Jr., a member of the governing board of Alere, Inc., the parent company of Petitioner (P. Ex. 6). Mr. Reamer's testimony largely addressed how

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[6] Even though CMS asserted that Petitioner had billed Medicare for providing diabetes supplies to 211 beneficiaries, it provided identifying information regarding only 47 claims in its October 5, 2016 letter. While I have no reason to doubt the veracity of CMS's assertion, I also recognize that by not identifying the other specific instances of purported abuse of billing privileges, Petitioner did not have an opportunity to respond to those allegations, to include submitting arguments and supporting evidence with its request for reconsideration. As such, I limit the discussion herein to the 47 claims identified by CMS in its October 5, 2016 correspondence. *See, e.g.*, *Neb Group of Arizona LLC*, DAB No. 2573 at 7 (2014); 42 C.F.R. § 498.56(e)(1) (limiting new documentary evidence at the ALJ level).

[7] While Petitioner requested expedited consideration of its request, I note that nearly two months elapsed between the notice of the reconsidered determination and the filing of a request for hearing.

Petitioner assesses Medicare eligibility and why Petitioner billed the claims for deceased beneficiaries to Medicare. P. Ex. 3. Mr. Reamer, while not specifically addressing the nine aforementioned claims, apparently referred to these nine claims when he stated that Petitioner's "Order Entry Team failed to identify the consumer's fraud[8] committed when an order was placed by an individual claiming to be the patient or an authorized caregiver, and mistakenly continued to process the order," and that "[t]hese claims were based purely on human error and were isolated, inadvertent order entry mistakes that no longer occur given the upgrades to Arriva's patient order entry systems." P. Ex. 3 at 11. Mr. Martinez discussed Arriva's access to HETS and that limitations of HETS resulted in billing errors, but did not reference any of the nine claims that are the focus of the present discussion. P. Ex. 5. The third witness, Mr. Roosevelt, discussed that, based on a telephone conversation with the then-Acting Administrator of CMS, Andy Slavitt, he felt that CMS held an incorrect belief that Petitioner was a successor of Liberty Medical Supply, a company that "declared bankruptcy in 2013 after being assessed with a Medicare overpayment in excess of $160 million." P. Ex. 6 at 3. Mr. Roosevelt explained that Petitioner purchased certain assets of Liberty at that time, but not its operations or liabilities. Mr. Roosevelt further explained that "I believe that [CMS] understood Arriva to be the successor of Liberty, rather than simply acquiring certain of its assets." P. Ex. 6 at 3. Mr. Roosevelt also testified that during the telephone conversation, CMS informed Petitioner that it "was one of the five largest claims appellants of all CMS contractors." P. Ex. 6 at 2. Mr. Roosevelt's conversation with Mr. Slavitt took place more than five weeks after the revocation became effective, on or about December 12, 2016. *Compare* P. Ex. 6 at 2 *with* CMS Ex. 1 at 1 (revocation effective November 2, 2016). Mr. Roosevelt appended email correspondence to his declaration, dated December 20, 2016, in which he contended that "CMS and its contractors seemed to have caused the problems," P. Ex. 6 at 6, and conceded that, "[i]n the end, according to its own regulations, CMS has full discretion on how to address this issue," P. Ex. 6 at 8. Mr. Roosevelt did not address the nine aforementioned claims, and contended that "Arriva is a model supplier for CMS." P. Ex. 6 at 7.

On February 25, 2017, Petitioner submitted a filing in which it stated that it would be requesting a subpoena to compel the testimony of three CMS employees, Zabeen Chong, Joel Cohen, and Minisha Hicks.[9] Petitioner's Witness List at 2-4. Mr. Cohen is the

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[8] I reiterate that Petitioner has not submitted evidence to support any allegation that these claims involved consumer fraud. Nonetheless, the issue of consumer fraud is irrelevant, as I have determined, for purposes of summary judgment, that these individuals could not properly approve a reorder of diabetes supplies for a deceased beneficiary. *See supra* at 4-5.

[9] Interestingly, Petitioner did not list Mr. Slavitt as a witness, even though Mr. Roosevelt's testimony is focused on a telephone conversation with Mr. Slavitt. P. Ex. 6.

signatory on the initial determination, CMS Ex. 1 at 2, and Ms. Hicks is the signatory on the reconsidered determination, CMS Ex. 2 at 5. Ms. Chong is the Director of CMS's Provider Enrollment & Oversight Group. Petitioner's Witness List at 2. With respect to these three witnesses, Petitioner stated, in its proposed witness list, that their testimony is necessary for the following reasons:

> (1) Whether CMS officials adopted a strict and improper interpretation of CMS's revocation authority, which would render the regulation facially invalid and mean that CMS acted outside of its regulatory authority in revoking Arriva's Medicare billing privileges; (2) to what extent CMS officials adequately reviewed the facts and circumstances of each of the 227 claims at issue, including whether to the best of Arriva's knowledge, the Medicare beneficiary was eligible to receive services, and to identify inaccuracies in the CMS data underlying the claims; (3) whether CMS officials considered a number of other highly relevant factors, including the accuracy and reliability of Medicare eligibility data, restrictions placed on Arriva's ability to access Medicare eligibility data, the frequency of billing errors in light of Arriva's volume of Medicare claims, and the lack of payment made to Arriva for any of the claims at issue; and (4) whether CMS officials improperly used CMS revocation authority to remove Arriva as a Medicare supplier to reduce the substantial Medicare claims appeal backlog that CMS has been ordered to process in a more timely manner.

Petitioner's Witness List at 2, 3, 4. In a subsequent motion for a subpoena to compel the testimony of these witnesses, filed on April 4, 2017, Petitioner requested the opportunity to examine these witnesses for largely the same reasons previously cited, but added that testimony is necessary to determine "to what extent CMS officials requested a result to the reconsideration prior to the completion of any meaningful review of the request and supporting materials." Motion for Issuance of Subpoenas at 6. With respect to Ms. Chong, Petitioner noted that she "leads the policy team at CMS that decided to revoke Arriva's Medicare billing privileges, and participated in a meeting with Arriva's representatives on November 23, 2016 to discuss CMS's revocation decision and Arriva's request for reversal or stay of the revocation in light of Arriva's unique facts and circumstances."[10] Motion for Issuance of Subpoenas at 2.

CMS filed an objection to Petitioner's motion for a subpoena on April 11, 2017. As I will grant CMS's motion for summary judgment, it is unnecessary to obtain any witness testimony, since the witness testimony is unrelated to any material facts that are in

[10] The fact the Ms. Chong participated in a meeting on November 23, 2016, is irrelevant. The initial determination was dated October 5, 2016. The reconsidered determination was dated November 4, 2016, and the revocation became effective that same date. Any meeting that took place subsequent to the effective date of the revocation is irrelevant.

dispute. Petitioner has conceded that on nine occasions it knew a Medicare beneficiary was deceased yet nonetheless obtained authorization for a reorder of diabetes supplies, shipped the beneficiary supplies, and then billed Medicare for those supplies. This practice occurred over the course of nearly a year, and each time Petitioner billed Medicare, its claims were promptly denied because the beneficiary was deceased at the time of service. Therefore, Petitioner was informed, on a recurring basis, that it had been shipping supplies to beneficiaries that it knew were deceased.

The question before me is whether CMS was authorized to revoke Petitioner's Medicare enrollment based on abusive billing practices pursuant to section 424.535(a)(8)(i). *Louis J. Gaefke, D.P.M.*, DAB No. 2554 at 11 n.10 (2013) (describing "whether CMS had a basis to revoke Petitioner's billing privileges under section 424.535(a)(8)" as "the ultimate issue" before the ALJ). In October 2016, CMS notified Petitioner that it would revoke its enrollment and provided a data sample of 47 claims involving the billing of Medicare for beneficiaries who were deceased on the dates of service. CMS Ex. 1. In response, while Petitioner raised a number of defenses and cast blame on CMS and the "caregivers" of its beneficiaries, it nonetheless acknowledged that in almost 20 percent of the sample of 47 claims, it knew that the beneficiary was deceased when it shipped diabetes supplies and billed Medicare for those supplies. Citing this admission, the reconsidered determination upheld the revocation established by the initial determination. CMS Ex. 2. The question before me is whether CMS had the authority to revoke Petitioner's Medicare enrollment pursuant to 42 C.F.R. § 424.535(a)(8) because Petitioner billed for services that could not have been furnished to a specific individual on the date of service. For purposes of summary judgment, Petitioner's admissions, alone, demonstrate an abuse of billing privileges. Any witness testimony could not disturb the undisputed facts of these nine instances. I therefore deny Petitioner's request for an oral hearing.

For the reasons explained below, summary judgment in favor of CMS is warranted.

II. Discussion

A. Issues

1. Whether summary judgment is appropriate;

2. Whether CMS has the authority to revoke Petitioner's billing privileges pursuant to 42 C.F.R. § 424.535(a)(8).[11]

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

[11] Petitioner's briefing does not raise any disagreement with the effective date of revocation or the length of the reenrollment bar.

The Social Security Act (Act) authorizes the Secretary of Health and Human Services (Secretary) to establish by regulation procedures for enrolling providers and suppliers in the Medicare program. 42 U.S.C. § 1395cc(j)(1)(A). The Secretary thereby has promulgated enrollment regulations. *See* 42 C.F.R. § 424.500 *et seq*. These regulations give CMS the authority to revoke the billing privileges of an enrolled supplier if CMS determines that certain circumstances exist. 42 C.F.R. § 424.535(a). Relevant to this case, CMS may revoke a provider's or supplier's billing privileges under the following circumstance:

> (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.
> (B) The directing physician or beneficiary is not in the state or country when services were furnished.
> (C) 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)(i). In addition to revocation, CMS must impose a bar on re-enrollment for a minimum of one year, but no more than three years. 42 C.F.R. § 424.535(c). CMS imposed a three-year re-enrollment bar. CMS Ex. 1 at 1.

A supplier may request reconsideration of the initial determination to revoke its billing privileges. 42 C.F.R. §§ 498.5(*l*)(1), 498.22(a). If dissatisfied with the reconsidered determination, the supplier may request a hearing before an ALJ. *Id.* § 498.5(*l*)(2). When appropriate, an ALJ may decide a case arising under 42 C.F.R. pt. 498 by summary judgment. *See* Civil Remedies Division Procedures § 19(a); *Livingston Care Ctr. v. U.S. Dep't of Health & Human Servs.*, 388 F.3d 168, 172 (6th Cir. 2004) (citing *Crestview Parke Care Ctr. v. Thompson*, 373 F.3d 743 (6th Cir. 2004)). Summary judgment is appropriate and an in-person hearing is not required if the record shows that there is no genuine dispute of any material fact and the moving party is entitled to judgment as a matter of law. *Senior Rehab. & Skilled Nursing Ctr.*, DAB No. 2300 at 3 (2010). To determine whether there are genuine issues of material fact for an in-person hearing, the ALJ must view the evidence in the light most favorable to the non-moving party, drawing all reasonable inferences in that party's favor. *Id.*

1. *Summary judgment is appropriate*.

A supplier whose enrollment has been revoked has a right to a hearing and judicial review pursuant to section 1866(h)(1) and (j) of the Act and 42 C.F.R. §§ 424.545(a); 498.3(b)(1), (5), (6), (8), (15), (17); 498.5. The Act requires a hearing on the record,

otherwise known as an oral hearing. Act §§ 205(b), 1866 (h)(1) and (j); *Crestview*, 373 F.3d at 748-51. A party may waive appearance at an oral hearing, but must do so affirmatively in writing. 42 C.F.R. § 498.66. Petitioner has not waived its right to an oral hearing or consented to a decision based only on the written record. Therefore, I cannot decide this case on the written record alone unless CMS's motion for summary judgment has merit.

Summary judgment is warranted only under certain circumstances. The procedures established by 42 C.F.R. pt. 498 do not include a summary judgment procedure. However, appellate panels of the Board have consistently recognized the availability of summary judgment in cases subject to 42 C.F.R. pt. 498, and the Board's interpretative rule has been acknowledged by the federal courts. *See, e.g.*, *Crestview*, 373 F.3d at 749-50. Furthermore, I have adopted a summary judgment procedure as a matter of judicial economy within my authority to regulate the course of proceedings. *See* Order, §§ 4, 11; 42 C.F.R. § 498.44.

Summary judgment is appropriate and no hearing is required if there are no disputed issues of material fact and the only questions that must be decided involve application of law to the undisputed facts or if the moving party must prevail as a matter of law even when all factual disputes are resolved in favor of the party against whom the motion is made. The Board has followed the general approach of the federal courts in determining whether summary judgment in lieu of a hearing is appropriate. The movant bears the initial burden of demonstrating that there are no genuine issues of material fact for trial and that the movant is entitled to judgment as a matter of law. When confronted with a properly supported motion for summary judgment, the nonmoving party "may not rest upon the mere allegations or denials of his pleading, but . . . must set forth specific facts showing that there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986) (quoting Fed. R. Civ. P. 56(e)); *see also* Fed. R. Civ. P. 56(c).

A nonmovant, in opposition to a motion for summary judgment, bears the burden of showing that there are material facts that are disputed either affecting the movant's prima facie case or that might establish a defense. It is insufficient for the nonmovant to rely upon mere allegations or denials to defeat the motion and proceed to hearing. The nonmovant must, by affidavits or other evidence that sets forth specific facts, show that there is a genuine issue for trial. If the nonmovant cannot show by some credible evidence that there exists some genuine issue for trial, then summary judgment is appropriate and the movant prevails as a matter of law. *Anderson*, 477 U.S. at 250. A test for whether an issue is regarded as genuine is if "the evidence [as to that issue] is such that a reasonable jury could return a verdict for the nonmoving party." *Id*. at 248. In evaluating whether there is a genuine issue as to a material fact, an ALJ must view the facts and the inferences to be drawn from the facts in the light most favorable to the nonmoving party. *Pollock v. Am. Tel. & Tel. Long Lines*, 794 F.2d 860, 864 (3rd Cir. 1986).

The standard for deciding a case on summary judgment and an ALJ's decision-making in deciding a summary judgment motion differ from resolving a case after a hearing. On summary judgment, the ALJ does not make credibility determinations, weigh the evidence, or decide which inferences to draw from the evidence, as would be done when finding facts after a hearing on the record. Rather, on summary judgment the ALJ construes the evidence in a light most favorable to the non-movant and avoids deciding which version of the facts is more likely true. *Holy Cross Vill. at Notre Dame, Inc.*, DAB No. 2291 at 5 (2009).

CMS argues that "it is undisputed that Petitioner submitted numerous claims for services to beneficiaries who were deceased on the dates of service." CMS Br. at 13. CMS further contends that "Petitioner does not dispute that it submitted forty seven (47) such claims, including nine claims where Petitioner admits it had information that the beneficiaries were deceased before mailing the supplies." CMS Br. at 1. Petitioner disputes CMS's argument that summary judgment is warranted because the undisputed evidence shows that it improperly billed Medicare for shipping supplies to deceased Medicare beneficiaries. P. Br. at 15-16. However, when CMS presented a list of 47 such instances, Petitioner *admitted* that it had knowingly billed for items provided to deceased beneficiaries on nine of those occasions. Reconsideration Request at 20-30. The undisputed evidence shows that Petitioner admitted that it "mistakenly continued to process the order" for each of the nine instances in which an eligibility check conducted prior to the date of reorder of supplies revealed that the beneficiary was deceased. Reconsideration Request at 7 n.4. Further, while Petitioner argued that these "isolated instances" occurred over a "short period of time during a systems change," the undisputed evidence shows that these nine instances occurred over the course of nearly a year. Reconsideration Request at 7 n.4; 20-30.

Likewise, Petitioner has argued there are "disputed issues of material fact in this case that preclude summary judgment," P. Br. at 28, but it has not submitted *any* evidence of disputed issues of material fact. Rather, Petitioner has identified issues of law that relate to the interpretation and application of the regulations that govern enrollment and billing privileges in the Medicare program and how those regulations are applied to the undisputed facts of this case. The issues in this case must be resolved against Petitioner as a matter of law, and summary judgment is appropriate such that an oral hearing is unnecessary.

Petitioner argues that the following "disputed issues of material fact" preclude summary judgment:

- Whether CMS officials adopted a strict and improper interpretation of CMS's revocation authority under 42 C.F.R. § 424.535(a)(8)(i), which would render the regulation facially invalid and mean that

CMS acted outside the scope of its regulatory authority in revoking Arriva's Medicare billing privileges.

- To what extent CMS officials adequately reviewed the facts and circumstances of each of the 227 claims at issue, including whether the services were properly ordered by Medicare beneficiaries or their caregivers and whether, to the best of Arriva's knowledge, the Medicare beneficiary was eligible to receive services, to make a reasonable determination about whether Arriva committed "abuse" of billing privileges or whether these were "isolated occurrences" or "accidental billing errors."

- To what extent CMS officials adequately reviewed the facts and circumstances of each of the 227 claims at issue to identify inaccuracies in the CMS data underlying the claims.

- Whether CMS officials adequately considered a number of highly relevant factors in determining whether Arriva committed "abusive" billing, including the accuracy and reliability of Medicare eligibility data, restrictions placed on Arriva's ability to access Medicare eligibility data, the frequency of billing errors in light of Arriva's volume of Medicare claims, and the lack of payment made to Arriva for any of the claims at issue.

- Whether CMS officials improperly used CMS's revocation authority under 42 C.F.R. § 424.535(a)(8)(i) to remove Arriva as a Medicare supplier to reduce the substantial Medicare claims appeal backlog that CMS has been ordered to process in a more timely manner.

P. Br. at 28-29. While I strain to understand how any of the points listed by Petitioner are "disputed issues of material fact," I recognize that Petitioner later clarifies that these are actually "factual questions." P. Br. at 29. Each one of the five "disputed issues of material fact" listed above is actually a question. If I were to answer each one of these questions in Petitioner's favor, it would make no difference to my determination of whether any *material facts* are in dispute, and would not erase that *Petitioner* has admitted to billing Medicare on at least nine occasions for providing supplies to beneficiaries it knew were deceased. Petitioner's own admissions, and the records Petitioner submitted supporting those admissions, constitute the undisputed material facts. Reconsideration Request at 3-9, 20-30; P. Ex. 4 at 1048-1051, 1053-1056, 1058-1061, 1063-1065, 1097-1100, 1134-1137, 1143-1146, 1148-1151, 1163-1166.

Petitioner's brief includes a three-page long statement of the facts of this case, but remarkably, Petitioner does not identify any facts that dispute the material facts involving the nine claims at issue. While Petitioner stated that it "had no knowledge that the Medicare beneficiaries were deceased on the date of service," it later recognized, with respect to the nine claims, that there was "inadvertent delay between when the beneficiary's status changed and when Arriva's internal systems were updated," thereby conceding that it improperly billed Medicare for those nine claims. P. Br. at 5.

Petitioner has only offered theories and speculation, without supporting evidence. Without more, Petitioner has not demonstrated there are disputed material facts. *See Med-Care Diabetic & Med. Supplies, Inc.*, DAB No. 2764 at 12 (2017) ("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." (citing *Senior Rehab. & Skilled Nursing Ctr.*, DAB No. 2300 at 3)). The only evidence Petitioner has submitted that even remotely supports its theories is the declaration by a member of Alere's governing board, Mr. Roosevelt. P. Ex. 6. In that declaration, Mr. Roosevelt expressed his opinion that the then-Acting CMS Administrator had confused Petitioner with another company that had a poor compliance history and that Mr. Slavitt incorrectly believed that Petitioner had a "'large volume of erroneous claims.'" P. Ex. 6 at 3. Petitioner paints the picture that such confusion about the number of erroneous claims, and Mr. Slavitt purportedly mistaking Petitioner for another apparently problematic company, demonstrates improper motive on the part of CMS in its revocation.[12]

While I accept Mr. Roosevelt's testimony as true, for purposes of summary judgment, this evidence does not show that there is a material fact in dispute. In fact, it may even have the opposite effect. Mr. Roosevelt reports that he initiated the call with the then-Acting CMS Administrator on or around December 12, 2016, "in [his] capacity as an Alere Governing Board Member." P. Ex. 6 at 2. The date of that telephone conversation was more than five weeks after the revocation became effective. At that time, Mr.

[12] I make no finding that the then-Acting Administrator of CMS had any such confusion regarding Petitioner's company, as expressed by Mr. Roosevelt. I note that the CMS Administrator (or Acting Administrator, in this instance) oversees programs involving 125 million beneficiaries and a budget of nearly a trillion dollars *https://www.cms.gov/about-cms/agency-information/performancebudget/downloads/fy2017-cj-final.pdf* and *https://www.hhs.gov/about/budget/fy2017/budget-in-brief/cms/index.html* (last visited April 18, 2017). Therefore, it is quite possible that, based on the wide-ranging responsibility and oversight of the CMS Administrator, the then-Acting Administrator was not fully briefed on Petitioner's case at the time of the telephone calls with Mr. Roosevelt.

Roosevelt discussed Petitioner's "hurdles" when checking Medicare beneficiary eligibility via HETS, which would have been a moot point on December 12, 2016. P. Ex. 6 at 2. Mr. Roosevelt stated, that "on or around December 12, 2016," the then-Acting Administrator was "not aware of Arriva's issue, and that he would look into it." P. Ex. 6 at 2. Mr. Slavitt, within a day or two, returned a call to Mr. Roosevelt, at which time Mr. Roosevelt reports that Mr. Slavitt apparently confused Petitioner with Liberty Medical and also stated that revocation was warranted due to a large volume of erroneous claims.[13] P. Ex. 6 at 3. That the then-Acting CMS Administrator was *not aware* of Petitioner's issues more than a month after its revocation seems to undermine Petitioner's claim that there was a plot by CMS to revoke Petitioner's enrollment in order to reduce the Medicare appeals backlog. Likewise, even if Mr. Slavitt somehow confused Petitioner with Liberty Medical, a company whose assets it acquired ("largely consisting of patient records"), Petitioner has not established that any such confusion by the then-Acting CMS Administrator more than two months after the initial determination to revoke Petitioner's enrollment had any impact on CMS's determination to revoke Petitioner's Medicare enrollment. P. Ex. 6 at 3.

Finally, while Petitioner has filed a motion for a subpoena to compel the testimony of Mr. Cohen, Ms. Hicks, and Ms. Chong, Petitioner's request amounts to nothing more than a fishing expedition in a lake without any fish. Petitioner has not produced *any* evidence that CMS revoked its enrollment for any reason other than its noncompliance with 42 C.F.R. § 424.535(a)(8)(i) as a result of its abuse of billing privileges by repeatedly billing Medicare for items provided to deceased beneficiaries. Petitioner admits that it seeks to question these witnesses regarding "whether" they incorrectly applied the pertinent law or considered immaterial factors in their decisionmaking. Motion for Issuance of Subpoenas at 2-6. As revocation of billing privileges is appropriate based on multiple admitted instances of billing abuse, Petitioner has not established that the testimony of these witnesses is relevant to the matters at hand.

For purposes of summary judgment, I have drawn all inferences in favor of Petitioner. For example, I accept, for purposes of summary judgment, that Petitioner contacted "caregivers" who approved the reorder of diabetes supplies for deceased beneficiaries. I also accept, for purposes of summary judgment, that Petitioner has at times had difficulties accessing the HETS system and did not always obtain the current information it was seeking regarding the status of beneficiaries. Likewise, I accept, for purposes of summary judgment, that the then-Acting Administrator of CMS may not have been fully informed about Petitioner's case on the two occasions he spoke with a member of Alere's governing board. Even assuming all of these facts in Petitioner's favor, I still conclude that Petitioner shipped and billed Medicare for sending supplies to nine beneficiaries who

[13] Owing to the fact that CMS alleged that Petitioner had submitted claims for 211 deceased beneficiaries, it appears that these could be the "erroneous" claims to which Mr. Slavitt was referring. CMS Exs. 1, 2.

it knew were deceased at the time of service. While Petitioner has raised *legal* arguments regarding its revocation, it has not identified any disputed material facts that counter its own admissions regarding the nine claims. Petitioner has contended that the errors were inadvertent and that its error rate is "miniscule." *See, e.g.*, P. Br. at 22. Likewise, Petitioner contends that it was targeted for revocation. However, Petitioner has not disputed the *material facts* at issue, namely, that it provided diabetes supplies to nine beneficiaries it knew were deceased and then billed Medicare for those supplies. Those are the material facts to which I will apply 42 C.F.R. § 424.535(a)(8)(i). This case turns on a matter of law and is therefore appropriate for summary judgment.

2. *The undisputed facts show that Petitioner billed Medicare for diabetic supplies that could not have been provided to nine beneficiaries on the specific dates of service.*

In support of its motion for summary judgment, CMS contends that Petitioner did not dispute that it had submitted claims for items and services provided to deceased beneficiaries, and that Petitioner acknowledged that it had provided diabetic supplies to all the deceased beneficiaries identified in the enclosure to the October 5, 2016 initial determination. CMS Br. at 4-5; *see* Reconsideration Request at 20-30. CMS argues, in pertinent part:

> With respect to the 47 claims identified in the revocation notice, Petitioner asserted that it furnished the supplies based on the information it had, and that Petitioner had not received any Medicare payment for those claims. Petitioner also submitted records that purported to show that for each of the 47 claims, Petitioner had furnished the supplies in response to a request from a beneficiary or a caregiver. Petitioner also submitted records showing that Medicare had denied the claims because the beneficiaries were deceased on the alleged date of service.

CMS Br. at 4-5 (internal citations omitted).

However, I note that even though Petitioner agreed that all 47 of the beneficiaries were deceased at the time of service, it argued that, for many of those claims, it did not know that the beneficiaries were deceased at the time of service. Reconsideration Request at 5-7. As previously mentioned, of those 47 claims, Petitioner acknowledged that it submitted claims for services provided to beneficiaries it knew were deceased in nine of those instances. Reconsideration Request at 7 n.4; *see* Reconsideration Request at 20-30. Petitioner explained that these were "isolated instances" that were "the result of internal systems limitations that, for a short period of time during a systems change, relied on Arriva personnel to manually update Arriva's billing systems with Medicare beneficiary status information." Reconsideration Request at 7 n.4.

Petitioner stresses that each of these nine instances resulted from an "inadvertent delay." P. Br. at 5; Reconsideration Request. While Petitioner has argued there were reasons for its billing errors, it has not presented any evidence to refute that it submitted claims for services that could not have been provided to a specific beneficiary because that beneficiary was deceased. Petitioner admitted the following:

> It billed for services to Beatrice on September 17, 2013, even though it had learned on September 1, 2013, that she was deceased;
>
> It billed for services to James on October 4, 2013, even though it had learned on September 1, 2013, that James was deceased;
>
> It billed for services to Marin on April 23, 2014, even though it had learned on April 1, 2014, that Marin was deceased;
>
> It billed for services to Douglas on April 30, 2014, even though it had learned on April 2, 2014, that Douglas was deceased;
>
> It billed for services to Richard on May 27, 2014, even though it had learned on May 1, 2014, that Richard was deceased.
>
> It billed for services to Elmer on June 20, 2014, even though it had learned on June 2, 2014, that Elmer was deceased;
>
> It billed for services to Marjorie on July 23, 2014, even though it had learned on July 2, 2014, that Marjorie was deceased;
>
> It billed for services to Clarence on August 19, 2014, and even though it had learned on August 1, 2014, that Clarence was deceased;
>
> It billed for services to Mae on August 20, 2014, even though it had learned on July 1, 2014, that Mae was deceased.

Reconsideration Request at 21, 22, 23, 25, 27, 28, 29, 30; P. Ex. 4. Petitioner has admitted it submitted claims for services that could not have been performed. Summary judgment is warranted.

3. *CMS has a sufficient basis to revoke Petitioner's Medicare billing privileges pursuant to 42 C.F.R. § 424.535(a)(8).*

CMS is authorized to revoke a supplier's Medicare billing privileges if that supplier "submits a claim or claims for services that could not have been furnished to a specific

individual on the date of service." 42 C.F.R. § 424.535(a)(8). As explained in detail already, the facts of this case show that Petitioner submitted claims for services that could not have been furnished to a specific individual on the date of service. Specifically, Petitioner obtained authorization for the reorder of diabetic supplies for deceased beneficiaries, shipped those supplies to the beneficiaries, and billed Medicare for those supplies. Reconsideration Request at 20-30. Therefore, the regulation authorizes CMS to revoke Petitioner's Medicare billing privileges.

For a number of reasons, Petitioner attempts to shift the blame for its actions. Petitioner contends that it had difficulty obtaining up-to-date beneficiary information from the Department of Health and Human Services's HETS database. However, with respect to these nine claims, Petitioner cannot shift the blame. Petitioner was able to successfully access the database in advance of contacting the beneficiaries to obtain approval for a refill of their diabetic supplies, and Petitioner knew that all of these nine beneficiaries were deceased before seeking approval for refills and shipping the supplies. Therefore, any difficulty that Petitioner reports in the process for verifying a beneficiary's status is irrelevant to the facts that support summary judgment.

Petitioner also argues that section 424.535(a)(8)(i) is inapplicable because Petitioner "is a mail-order supplier that has no face-to-face contact with beneficiaries and often appropriately (and by Medicare rules) furnishes its covered services up to two weeks after having received a request from the beneficiary or caregiver." P. Br. at 9-10. This contention is not persuasive; in the nine instances at issue, it makes no difference that Petitioner did not have any face-to-face contact with the beneficiaries. Petitioner knew that these nine beneficiaries were deceased, and its status as a mail-order company is irrelevant. Even though Petitioner knew the beneficiaries were deceased, it nonetheless shipped these beneficiaries supplies and billed Medicare for those supplies. The facts, as relevant here, do not raise a distinction between a face-to-face supplier and a mail-order supplier. Further, the regulation makes no distinction between face-to-face suppliers and mail order suppliers. *See Med-Care Diabetic & Med. Specialties*, DAB No. 2764 at 12 ("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.").

Petitioner, in arguing that the regulation is inapplicable to mail-order companies, contends that a response to a public comment indicates that section 424.535(a)(8)(i) "cannot be meant to be applied in the same way to mail-order suppliers, such as Arriva, which do not have face-to-face contact with Medicare beneficiaries, as it might be applied to providers who provide services in a face-to-face manner." P. Br. at 12. Petitioner argues that the reference to "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

service had been furnished" evidences that the regulation did not contemplate a mail-order supplier. P. Br. at 12 (quoting 73 Fed. Reg. 36,448, 36,455 (June 27, 2008)). However, Petitioner fails to address a subsequent sentence of that same passage, which states: "Rather, this basis for revocation is directed at providers and suppliers who are engaging in a pattern of improper billing," which does not provide any limitation to only face-to-face providers and suppliers. 73 Fed. Reg. at 36,455. Further, Petitioner acknowledges that "Arriva's policy is to comply with Medicare guidance that directs suppliers to contact a Medicare beneficiary regarding refills of supplies no sooner than 14 days prior to a shipment." P. Ex. 3 at 12 (citing Medicare Program Integrity Manual (MPIM), § 4.26). Interestingly, CMS's policy guidance regarding the regulation, as cited by Petitioner, does not distinguish between face-to-face and mail order suppliers. Further, the public comment prompting the response articulated that there was "not enough guidance given to the contractors . . . which could cause overburdened contractors to implement this policy too widely." 73 Fed. Reg. at 36,455; *see* 42 C.F.R. § 424.535(a) (Discretionary language that "CMS *may* revoke a currently enrolled provider or supplier's Medicare billing privileges . . . ." (emphasis added)). The context of the statement, therefore, shows that it is guidance to CMS contractors rather than a rule that is enforceable against CMS. *See In re CMS LCD Complaint: L29288*, DAB No. 2499 at 4 (2013) (stressing the importance of determining the context of a *response* to public comments in the preamble to a final rule); *see Med-Care Diabetic & Med. Supplies*, DAB No. 2764 at 11 (noting this response was "[i]n response to an inquiry about the guidance CMS would provide to contractors and the likelihood that contractors would be overburdened by the need to review voluminous claims for possible abusive billing").

Petitioner relies on the title of section 424.535(a)(8), "Abuse of billing privileges," for its position that CMS must show Petitioner intended to submit improper claims. P. Br. at 8-9. Petitioner claims that "there must be some 'abuse' committed by the provider or supplier in its billing practices to fall within the regulation." P. Br. at 8. Petitioner argues that "mere inadvertent mistakes or human error in claims submission cannot qualify as 'abuse' that warrants the severe penalty of revocation of Medicare billing privileges." P. Br. at 8. However, the title to a section or subsection is not controlling, does not add elements to the operative language, and may only be used as an interpretative aid. *See Bhd. of R.R. Trainmen v. Balt. & Oh. R.R. Co.*, 331 U.S. 519, 528-29 (1947); *Ellen L. Morand*, DAB No. 2436 at 8 (2012) ("General principles of statutory construction provide that the title of a statutory provision should not be read in a manner that limits the plain meaning of the statutory text.") (citations omitted). The text of section 424.535(a)(8) does not mention the word "abuse." Accordingly, neither "abuse" nor "abusive billing practices" (however a particular supplier might define them) are required before CMS is authorized to revoke Petitioner's billing privileges pursuant to 42 C.F.R. § 424.535(a)(8)(i). *See Louis J. Gaefke, D.P.M.*, DAB No. 2554 at 8 ("Given the absence from the regulation of any requirement to show fraudulent intent, or exceptions for inadvertent error, the preamble cannot be read in a manner that would

effectively bar CMS from taking action against providers or suppliers who submit multiple improper claims, even where the claims were the result of negligence or reckless indifference by the provider or supplier.")

Petitioner explains that the preamble of the final rule published in the Federal Register discussed that revocation was not intended for "isolated occurrences or isolated billing errors." P. Br. at 8-9 (quoting 73 Fed. Reg. at 36,455). That is correct, and the language of the regulation, in providing the definition of "abuse" within the regulation, did not target "isolated occurrences or isolated billing errors." *See Access Foot Care, Inc., & Robert Metnick, D.P.M*, DAB No. 2752 at 9 (2016) ("The preamble to the Final Rule does provide guidance as to what may show a pattern of abusive billings by stating CMS will *not* revoke Medicare billing privileges for improper billing *unless* the improper billing consists of 'multiple instances' of abusive billing."). Rather, the language of the regulation shows that it targets more egregious incidents in which "[t]he 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" and gives examples such as the beneficiary being deceased on the date of service, the directing physician or beneficiary not having been present in the state or country when services were furnished, or the equipment necessary for testing not having been present where the testing is said to have occurred. 42 C.F.R. § 424.535(a)(8)(i). These situations involve essentially logistical impossibilities, and the statements in the preamble at most articulate CMS's enforcement policy and do not create extra-regulatory essential elements that must be proven to uphold a revocation action based on section 424.535(a)(8).

This interpretation is supported by the fact that the text quoted from the preamble directly contradicts the plain language of the regulation. The regulation authorizes CMS to revoke a supplier's billing privileges after that supplier submits "*a claim* or claims" for services that could not have been provided. 42 C.F.R. § 424.535(a)(8)(i) (emphasis added). Based on the face of the regulation, a single claim can trigger CMS's authority to revoke a supplier's billing privileges. However, the preamble more permissively states that CMS "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." 73 Fed. Reg. at 36,455.

Even if the language in a preamble conflicts with the plain language of the regulation, the regulatory language, which in this instance is clear, must prevail. *Cf. Ass'n of Am. R.R. v. Costle*, 562 F.2d 1310, 1316 (D.C. Cir. 1977) ("Where the enacting or operative parts of a statute are unambiguous, the meaning of the statute cannot be controlled by language in the preamble."). Had a change to the basis for revocation under section 424.535(a)(8) been intended in the final rule, the regulatory text could have been modified to require a finding of three or more instances of abusive billing practices. *See In re CMS LCD Complaint: L29288*, DAB No. 2499 at 5 ("Had the intent been to exclude specialist physicians from certifying medical necessity, different wording could have easily

accomplished that result."). No such change was made. Further, a duly promulgated regulation has the force and effect of federal law. *See Chrysler Corp. v. Brown*, 441 U.S. 281, 295-96 (1979). I am bound to apply the regulatory text even if it is more broadly worded than the statements in the preamble to the final rule. *Cf. CMS LCD Complaint: L29288*, DAB No. 2499 at 5.

Petitioner argues that "the identified error rate reflects an almost 'six sigma' quality of performance—the recognized gold standard for organizational performance" and that it has a miniscule error rate. P. Br. at 22. First, the applicable regulatory section, 42 C.F.R. § 424.535(a)(8)(i), is not triggered based on a threshold *percentage* of abusive billing. *Patrick Brueggeman, D.P.M.*, DAB No. 2725 at 12 (2016), and cases cited therein. Rather, noncompliance exists when 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." 42 C.F.R. § 424.535(a)(8)(i). While the plain language of the regulation allows for a finding of abuse of billing privileges based on a single instance, CMS has explained that it will exercise its revocation authority only when there are "multiple instances, at least three, where abusive billing practices have taken place." 73 Fed. Reg. at 36,455; *see John P. McDonough III, Ph.D., Geriatric Psychological Specialists, & GPS II, LLC*, DAB No. 2728 at 8 (2016) ("We conclude that the plain language of the regulation sufficed to notify Petitioners that the submission of a claim for services that could not have been provided to the specific individual identified in the claim on the date of service was an abuse of billing privileges that could lead to revocation, and the preamble provided notice that the submission of at least three such claims would not be viewed as merely accidental.").

Further, Petitioner's reliance on its purported six sigma level quality of performance is misplaced, and the evidence does not support such an elite level of performance. Petitioner creatively presents statistics to argue that it has an error rate of 0.0003% by taking the total of 5.8 million claims it submitted to Medicare over a five-year period and the 227 instances of abusive billing identified by CMS. However, this statistical analysis is flawed. *See Patrick Brueggeman, D.P.M.*, DAB No. 2725 (discussing that neither the regulation nor the preamble suggest any requirement for a minimum claims error rate).[14] After all, Petitioner is in the health care business rather than the mortuary business, and one would expect that the overwhelming majority of the 5.8 million claims submitted by Petitioner involved shipments of supplies to living people. Neither party disputes that the 227 cases identified by CMS consisted of a "sample," meaning that based on the parameters utilized for data analysis, it is certainly possible that, based on a different sampling with wider parameters, a greater number of improperly billed claims could have been identified. CMS listed only 47 specific instances in its October 5, 2016 initial

[14] A more informative metric, for purposes of this analysis, may be the percentage of deceased beneficiaries that Petitioner, in advance of shipping supplies, had correctly determined were deceased.

determination, and Petitioner readily admitted that it had improperly billed Medicare in 9 of those instances. Thus, taken from a sample size of only 47 cases, Petitioner admitted to improper billing in almost 20 percent of those cases.

Petitioner also argues that it did not receive payment for these claims, and if it did receive payment, it refunded the payments. P. Br. at 23. However, revocation pursuant to section 424.535(a)(8)(i) is based on abusive billing, and a supplier's return of improperly received reimbursement or that the Medicare contractor caught the error prior to issuing payment is irrelevant.

Petitioner also argues that the revocation of its enrollment based on its "billing for services furnished to deceased beneficiaries is a mere pretext for CMS's true motivation for kicking [it] out of the Medicare program," and that the revocation was prompted by Petitioner's "volume of claims appeals" that "contribute to the significant backlog that the government has been ordered to clear by 2020 . . . ." P. Sur-reply at 11 (emphasis and capitalization omitted). Petitioner explains that it "has been forced to appeal approximately 250,000 errantly denied claims over the past five years due to massive CMS audits," and that it is therefore a party to a large number of appeals that constitute the current backlog, which it reported totaled 687,382 claims as of the end of fiscal year 2017.[15] P. Sur-reply at 11-12. Petitioner presents no evidence showing that its revocation is based on anything other than its own abuse of billing privileges.

In support of this accusation, the only *evidence* Petitioner submits is the testimony of Mr. Roosevelt, a member of Alere's governing board. P. Ex. 6. Mr. Roosevelt, in his written testimony, provides a number of statements that appear to be his own assumptions of what he "understood" Mr. Slavitt believed about Petitioner, but ultimately, Mr. Roosevelt did not testify that Mr. Slavitt actually stated that revocation was for any purpose other than for abusive billing. For example, Mr. Roosevelt stated that "I believe Mr. Slavitt understood Arriva to be the successor to Liberty, rather than simply acquiring certain of its assets." P. Ex. 6 at 3. Mr. Roosevelt admitted that "Mr. Slavitt did not express any other reasons for the revocation," but reported that he "understood Mr. Slavitt to mean that the appeals volume was the main reason for CMS's focus on Arriva's minor billing issues as a basis for revocation of the supplier number."[16] P. Ex. 6 at 3.

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[15] As Petitioner acknowledges it has many pending appeals, it is unclear why it apparently takes issue with Mr. Slavitt's reference to its many pending appeals. Even if Petitioner has an 85 percent success rate on appeal, as it claims, that means that it will lose more than 37,000 of its 250,000 appeals. *See* P. Ex. 6 at 7.

[16] I disagree that the repeated billing for items provided to deceased beneficiaries is a "minor" billing problem. Likewise, it appears that the witness does not understand the gravity of the noncompliance, in that the same witness stated that Petitioner is a "model supplier for CMS." P. Ex. 6 at 7.

Finally, Petitioner fails to take any responsibility for its errors. While Petitioner blames such factors as access to HETS, it fails to recognize that the practice it used for obtaining authorization for refills, at least in part, caused these errors. As acknowledged by Petitioner, Section 4.26.1 of the MPIM (Revision 641, Implemented March 19, 2016), requires that DMEPOS suppliers contact a "beneficiary or designee"[17] prior to dispensing a refill:

> 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.

The purpose of this requirement is to "ensure that the refilled item is necessary and to confirm any changes/modifications to the order." MPIM, § 4.26.1. Thus, even if a beneficiary's death has not yet been reported to a database, or the supplier somehow did not record that the beneficiary was deceased, the contact to the beneficiary or designee is a means to ensure that refills are necessary. *See* MPIM, § 5.2.8 (Revision 641, Implemented March 19, 2016) (stating that beneficiaries must be contacted prior to dispensing a refill "to ensure that the refilled item remains reasonable and necessary, existing supplies are approaching exhaustion, and to confirm any changes/modifications to the order"). Refills of DMEPOS products may be expensive and also require a prescription; these policies prevent unnecessary and costly refills and also prevent these products from getting into the wrong hands. Further, as relevant here, in ensuring that a refill is necessary, the supplier would ensure that the beneficiary is still alive. It appears that it is a common practice for Petitioner, as occurred in all but one of these nine claims, to make a "robo call" to each beneficiary in order to obtain approval of a refill or refills through its automated system. However, it is clear that none of the nine deceased beneficiaries answered the automated telephone calls. As Petitioner relied on automated calls in eight of these instance, rather than person-to-person interaction, it is not clear how Petitioner accurately ascertained whether the individual authorizing the reorder was a "designee" who would be authorized to approve a reorder of supplies. Further, Petitioner's records of automated telephone calls do not identify the name of the designees but rather indicate that an unnamed "patient/caregiver" approved the reorders.

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[17] The same section defines a beneficiary as "[a]ny person who can sign and accept the delivery of durable medical equipment on behalf of the beneficiary."

It is also unclear whether the automated system gave the beneficiary's complete identifying information during the telephone call, thereby leaving open the possibility that the recipient of the telephone call would unwittingly approve a reorder because he or she did not know that the request involved a deceased beneficiary. Although the automated system likely enabled Petitioner to refill more prescriptions using less staff resources, it quite possibly contributed to Petitioner's failure to receive accurate information when it telephonically obtained authorization for refills. While such a practice for obtaining authorization for refills may meet the technical requirements of CMS and its contractors, its use by Petitioner had vulnerabilities, in that Petitioner did not successfully elicit information about the beneficiary's death in any of these instances.[18]

While Petitioner boasts of "six sigma" quality through a favorable calculation of its error rate, it fails to recognize that a system that it created to maximize refills and promote automated contacts failed to yield critical information that refills were not "reasonable and necessary" because the beneficiaries were deceased. MPIM, § 5.2.8. CMS need only show that Petitioner submitted a claim or claims for services that could not have been provided to a specific individual on the date of service. CMS has undeniably made such a showing in this case by way of Petitioner's own admissions.

4. *The effective date of the revocation of Petitioner's billing privileges is November 4, 2016.*

The revocation of Medicare billing privileges is effective 30 days after CMS or its contractor issues the notice of revocation, unless certain exceptions apply. 42 C.F.R. § 424.535(g). The effective date of Petitioner's revocation is November 4, 2016.

III. Conclusion

For the reasons explained above, I grant summary judgment in favor of CMS. There is no genuine dispute of material facts and CMS is entitled to judgment affirming its revocation of Petitioner's Medicare billing privileges. I affirm CMS's revocation of Petitioner's Medicare billing privileges, effective November 4, 2016.

/s/
Leslie C. Rogall
Administrative Law Judge

[18] While Petitioner's use of automated telephone calls did not yield information that eight beneficiaries were deceased at the time of telephone contact, I need not address whether this practice, in general, is appropriate.