Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Zille Shah, M.D., and Zille Huma Zaim, M.D., PA
Docket No. A-16-13
Decision No. 2688
April 19, 2016

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Petitioner Zille Shah, M.D., and Zille Huma Zaim, M.D., PA, (Petitioner)[1] appeals an Administrative Law Judge (ALJ) decision upholding on summary judgment the Centers for Medicare & Medicaid Services' (CMS) determination to revoke Petitioner's Medicare enrollment and billing privileges under 42 C.F.R. § 424.535(a)(8). *Zille Shah, M.D., and Zille Huma Zaim*, M.D., PA, DAB CR4243 (September 22, 2015). The ALJ concluded that the revocation was authorized under that regulation because Petitioner submitted or caused to be submitted claims for Medicare reimbursement for services she could not have provided on the claimed service dates. For the reasons stated below, we affirm the ALJ Decision.

Background[2]

The legal basis for the revocation

CMS, through Novitas Solutions (Novitas), a CMS Medicare contractor, revoked Petitioner's Medicare enrollment and billing privileges based on 42 C.F.R. § 424.535(a)(8), which authorizes CMS to revoke where it finds an abuse of Medicare billing privileges. As of October 30, 2014 (the date of Petitioner's revocation), the regulation provided as follows:

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[1] The ALJ explained that the two names in the case identify one individual who enrolled in Medicare as an individual physician and as a professional association. The ALJ referred to the individual as Petitioner and "her," and we do the same. *See* ALJ Decision at 1 n.1.

[2] Unless otherwise indicated, the facts stated in this section reflect the findings in the ALJ Decision and/or undisputed facts of record.

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

42 C.F.R. § 424.535(a)(8). On its face, the language "claim or claims" would authorize revocation for abuse of billing privileges based on the filing of a single claim for services that could not have been provided on the claimed date of service. However, the regulation's preamble indicates that CMS has chosen not to revoke unless at least three such claims are submitted. 73 Fed. Reg. 36,448, 36,455 (June 27, 2008). Providers and suppliers whose enrollment and billing privileges are revoked are subject to a re-enrollment bar of from one to three years. 42 C.F.R. § 424.535(c).

The revocation history

Petitioner, a physician, participated as a supplier in the Medicare program.[3] On September 30, 2014, Novitas issued an initial determination revoking Petitioner's Medicare enrollment and billing privileges under 42 C.F.R. § 424.535(a)(8) for abuse of billing privileges. CMS Ex. 5, at 9-10. The initial determination letter stated that Medicare claims data and Department of Homeland Security records revealed that Petitioner "submitted in excess of 90 Medicare claims for services rendered during documented periods of travel outside of the United States." *Id*. at 9. The documented periods of travel outside the United States listed in the letter were June 18-June 20, 2011; September 27-October 2, 2011; May 2-May 4, 2012; and May 20-June 4, 2013. *Id*. The initial determination letter notified Petitioner of her rights to file a corrective action plan and to seek reconsideration of the initial determination and further stated, "You may submit additional information with the reconsideration that you believe may have a bearing on the decision." *Id*. at 9-10. Finally, the letter told Petitioner that Novitas was establishing a three-year reenrollment bar. *Id*. at 10.

On December 4, 2014, Petitioner submitted a corrective action plan to Novitas. CMS Ex. 6, at 3-6. On December 30, 2014, Novitas rejected the plan, on the ground that the plan "gives an explanation of the circumstances, but does not negate the fact that claims were submitted for services that could not have been furnished by you on the dates of service reported." *Id*. at 1.

[3] The regulations define "supplier" to mean "a physician or other practitioner, or an entity other than a provider, that furnishes health care services under Medicare." 42 C.F.R. § 400.202.

On December 4, 2014, Petitioner also sought reconsideration of the initial determination. CMS Ex. 5, at 3-6. Referring to Novitas's notice that Petitioner "'submitted in excess [of] ninety Medicare claims during documented periods of travel outside of the United States' for the periods of time [specified in the initial determination letter]," Petitioner admitted she "was out of the country for those dates," but stated that "the last date of 05/20/13-06/04/13 was correctly billed and was billed under my nurse practitioner[']s . . . [billing] number and not my [billing] number." *Id*. at 5. Petitioner further stated that she "became aware of the discrepancies in my billings sometime in January of 2013 . . . only used nurse practitioners when I was out of town . . . and ha[d] taken a variety of measure to ensure that there will not be any future billing errors on my part or abuse of my [billing] number . . . ." *Id*. at 5-6. On March 4, 2015, Petitioner submitted a supplemental reconsideration letter in which she referred to "being suspended due to the fact that I submitted Medicare claims for periods that I was outside the United States" and stated that "it was not done with any intention to defraud the Medicare program." CMS Ex. 3, at 7.

On March 31, 2015, Novitas denied Petitioner's request for reconsideration, concurring with the initial determination and stating that "[Petitioner] w[as] in violation of Medicare guidelines when claims were submitted for services rendered during documented periods of travel outside of the United States." CMS Ex. 1, at 3. The letter further stated that Petitioner's alleged "[i]gnorance of Medicare policy" did not eliminate her accountability for the use of her billing number and that she "had not submitted evidence that would cause CMS to overturn the initial determination." *Id*. Petitioner then filed the hearing request that led to the ALJ Decision.

Principal ALJ Findings

The ALJ found that the undisputed facts established that Petitioner was out of the country from June 18-June 20, 2011; September 27-October 2, 2011; May 2-May 4, 2012; and May 20-June 4, 2013. ALJ Decision at 4. The ALJ also found that Petitioner submitted to Medicare claims for reimbursement for services allegedly provided by her on those dates. *Id*., citing CMS Ex. 1, at 1-5; CMS Ex. 8, at 6-72. The ALJ found that "Petitioner admits being out of the country on the dates that are at issue, and she admits additionally that she submitted or caused to be submitted claims for services that were ostensibly provided by her on those dates." *Id*., citing CMS Ex. 5, at 5. The ALJ noted that while Petitioner questioned whether the total number of improper claims was as high as CMS alleged (more than 90 in total), Petitioner "does not deny that she submitted some unspecified number of claims for services that she could not have provided on the claimed service dates." *Id*. at 5. The ALJ said that the three-claim threshold the preamble stated was not a legal requirement but that, in any event, "there is no doubt that

[Petitioner] submitted or caused to be submitted more than three [improper claims]." *Id.* The ALJ concluded that while Petitioner made a number of arguments "intended to deflect blame for the false claims that she submitted or caused to be submitted . . . what Petitioner *does not deny* is that she was out of the country for periods of time and that she submitted or caused to be submitted claims for services that she allegedly provided on dates when she was not in the United States. That concession is all that CMS needs in order to authorize revocation of Petitioner's participation." *Id.* (emphasis in original). Finally, the ALJ rejected the "basic misconception that underlies Petitioner's arguments . . . that there must be proof of culpability to justify revocation pursuant to 42 C.F.R. § 424.535(a)(8)." *Id.*, citing *Louis J. Gaefke, D.P.M.*, DAB No. 2554, at 5-6 (2013).[4]

Standard of Review

We review the ALJ's grant of summary judgment de novo, construing the facts in the light most favorable to Petitioner and giving her 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). Summary judgment is appropriate when there is no genuine dispute about a fact or facts material to the outcome of the case and the moving party is entitled to judgment as a matter of law. *Id.*; *Celotex Corp. v Catrett*, 477 U.S. 317, 322-25 (1986). The party moving for summary judgment (here, CMS) has the initial burden of demonstrating that there is no genuine issue of material fact for trial and that it is entitled to judgment as a matter of law. *Celotex*, 477 U.S. at 323. If the moving party carries that burden, the non-moving party must "come forward with 'specific facts showing that there is a genuine issue for trial.'" *Matsushita Elec. Industrial Co., LTD. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (quoting Rule 56(e) of the Federal Rules of Civil Procedure). Our standard of review on a disputed conclusion of law is whether the ALJ decision is erroneous. *See Guidelines — Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's or Supplier's Enrollment in the Medicare Program*, http://www.hhs.gov/dab/divisions/appellate/guidelines/prosupenrolmen.html.

[4] In *Gaefke*, the Board found no error in the ALJ's rejection of the supplier's argument that "the title of the regulation, 'Abuse of billing privileges,' . . . means that there must be a level of intent that is not stated in the regulation itself . . . ." DAB No. 2554, at 8. The Board relied on "[t]he plain language of the regulation [which] contains no requirement that CMS establish that the supplier acted with fraudulent or dishonest intent." *Id.* at 7. "The regulatory language," the Board continued, "also does not provide any exception for inadvertent or accidental billing errors." *Id.* As in *Gaefke*, we find no error in the ALJ's rejection here of Petitioner's argument that proof of culpability is required to revoke under section 424.535(a)(8).

Discussion

A. <u>The ALJ applied the correct legal standards</u>.

Petitioner argues that the ALJ did not apply the correct legal standards when he concluded that CMS was authorized to revoke Petitioner's enrollment and billing privileges under section 424.535(a)(8) . Request for Review (RR) at 5-9. We conclude for the reasons stated below that the ALJ applied the correct legal standards and properly concluded that the revocation was lawful.

1. Summary judgment was appropriate since there was no dispute about the material facts.

Petitioner first alleges that "CMS failed to meet its burden to obtain summary judgment." RR at 5. We disagree and conclude that the ALJ properly granted summary judgment to CMS. As stated above, summary judgment is proper when there is no genuine dispute about any fact material to the outcome of the case. CMS revoked Petitioner's enrollment and billing privileges under section 424.535(a)(8) because CMS concluded she had abused those billing privileges by filing multiple claims for services that she could not have furnished to specific individuals on the dates claimed because she was out of the country. Accordingly, the facts material to the ALJ's decision, and to our de novo review, are 1) whether Petitioner was out of the country on the dates alleged and 2) whether she billed Medicare for services she claimed to have provided to specific individuals on those dates.

As indicated above, under the summary judgment standard, CMS had the initial burden to come forward with evidence on these facts. CMS clearly met that burden. CMS submitted evidence, including Department of Homeland Security records, showing that Petitioner was out of the country from June 18-20, 2011; September 27-October 2, 2011; May 2-4, 2012; and May 20-June 4, 2013. CMS Ex. 7, at 1; CMS Ex. 8, at 68-72. CMS also submitted Medicare claims data showing that Petitioner submitted more than 90 claims for services she claimed to have provided to Medicare patients on the dates she was out of the country. CMS Ex. 7 at 1; CMS Ex. 8, at 6-72. The ALJ cited this evidence and further found that Petitioner did not deny that she was out of the country on the dates in question or that she submitted multiple claims for services ostensibly provided by her on those dates. ALJ Decision at 4, 5 (citations omitted).

Petitioner's request for review does not directly challenge the ALJ's findings regarding these undisputed facts. Moreover, the record before the ALJ (which is the record for our review) shows that Petitioner admitted to the facts on which CMS based the revocation. In her request for reconsideration, Petitioner referred to Novitas's initial determination

letter that identified dates when she was out of the country and stated that she had nonetheless billed for services furnished on those dates. CMS Ex. 5, at 5. Petitioner then conceded, that she "was out of the country for those dates" and acknowledged that she was "aware of the discrepancies in my billings" and took "measures to ensure that there will not be any future billing errors on my part or abuse of my [billing] number . . . ." *Id.* at 5-6. Petitioner also submitted a supplemental reconsideration letter in which she referred to "being suspended due to the fact that I submitted Medicare claims for periods that I was outside the United States" and explained that "it was not done with any intention to defraud the Medicare program." CMS Ex. 3, at 7.

Petitioner's Request for Review also does not challenge the ALJ's finding that while Petitioner questioned whether the total number of improper claims she submitted was as high as CMS alleged she "does not deny that she submitted some unspecified number of claims for services that she could not have provided on the claimed service dates." ALJ Decision at 5. Petitioner alleges, as she did below, that when she was out of the country in 2013, the nurse practitioner furnishing the services in her absence used her own billing number. RR at 9; CMS Ex. 5, at 5. The exhibits cited by Petitioner in support of this allegation were not admitted to the record and, thus, are not evidence before us. However, even assuming her allegation is true, this would not affect our decision since Petitioner does not deny that she was out of the country for the remaining periods of time identified by CMS and billed for multiple services under her own billing number during those periods. In sum, while disputing the total number, Petitioner does not provide evidence establishing how many claims she alleges were not submitted as CMS charged, and certainly does not allege that they were fewer than the three instances of improper billing posited as a threshold in the preamble.[5]

Petitioner also does not challenge the ALJ's specific finding that "whether Petitioner submitted at least 90 false claims or somewhat fewer than that number, there is no doubt that she submitted or caused to be submitted more than three of them." Since Petitioner does not dispute that her improper claims exceeded the three-claim threshold stated in the preamble to section 424.535(a)(8), we need not address the legal effect, if any, of the preamble language when compared to the language of the regulation.

[5] The record contains an affidavit from a CPA that states, among other things, an "Analysis of Government's Alleged Loss." P. Ex. 16 (Lamar Blount Affidavit). The CPA states that the claims data in CMS Exhibit 8 included "30 claims with dates of service outside of the dates in question." *Id*. at 6. Petitioner does not even cite this statement much less assert that it establishes some total number of claims smaller than that identified by CMS. However, even assuming the CPA's assertion about 30 erroneously listed claims is correct, the error would not obviate the undisputed fact that the claims filed for services provided while Petitioner was out of the country substantially exceeded the three-claim threshold CMS has set for a revocation action under section 424.535(a)(8).

Petitioner argues that the evidence presented by CMS, including the declaration by the OIG inspector, is unreliable hearsay, but Petitioner is not specific and does not explain this assertion. RR at 6. The ALJ noted a similar lack of explanation or specificity when he overruled Petitioner's argument that CMS's evidence should not be admitted because, according to Petitioner, the Medicare claims records were "'incomprehensible' or not credible and reliable" and the OIG inspector declaration was "not credible." ALJ Decision at 2. The ALJ stated --

> I need not address that argument [about the inspector's affidavit] in order to issue summary judgment favorable to CMS because CMS did not rely on anything in the affidavit to establish facts that are in dispute. As I will explain, Petitioner admits that she was out of the country during periods of time when she claimed reimbursement for services that she ostensibly provided to Medicare beneficiaries. Additionally the claims are not incomprehensible. I note, additionally, that Petitioner does not deny filing, or causing to be filed, any of the claims that are identified in the exhibit. Petitioner has not explained its credibility and reliability objections and I overrule them for that reason.

Id. For all of the reasons stated above, we reject Petitioner's arguments that the ALJ erred by relying on CMS's evidence in support of summary judgment.[6] In summary, we conclude that the ALJ did not err in deciding this case on summary judgment given the absence of any dispute of material fact.[7]

2. The ALJ did not err in finding a violation of section 424.535(a)(8) regardless of whether services were actually provided by the nurse practitioner on the dates Petitioner was not in the country.

Petitioner argues that because services were actually provided on the dates she was out of the country, albeit by the nurse practitioner rather than herself, CMS did not have the

[6] Petitioner makes the same assertions about the alleged unreliability of CMS's evidence in her argument that "The [ALJ] Decision is Not Supported By Substantial Evidence." RR at 10-11. These arguments are equally baseless there, indeed, more so since "substantial evidence" is not the standard of review that applies to the Board's review of a decision made on summary judgment.

[7] In light of this conclusion, we must summarily reject Petitioner's argument that she "was denied a hearing and right to cross examine." RR at 13. Petitioner had no right to an evidentiary hearing since the ALJ properly concluded that there were no disputes about material facts needing resolution in such a hearing.

authority to revoke under section 424.535(a)(8).[8] Petitioner relies on an ALJ decision in *Velocity Healthcare Servs., LLC*, DAB CR3849 (2015), and faults the ALJ here for not commenting on that case. RR at 6-7. Petitioner further relies on a statement by CMS in the preamble to 2015 amendments to section 424.535(a)(8) that it "currently does not have the ability to revoke a provider or supplier's billing privileges based on a pattern or practice of submitting noncompliant claims." RR at 7. Neither *Velocity* nor the preamble statement provides any support for Petitioner.

The ALJ committed no error in not addressing *Velocity*. Apart from the fact that ALJ decisions do not bind other ALJs or the Board, *e.g. Britthaven of Chapel Hill*, DAB No. 2284, at 9-10 (2009), *Velocity* is inapposite and irrelevant. In *Velocity*, CMS did not revoke the supplier's (an ambulance company) billing privileges under the provision of section 424.535(a)(8) that is at issue here, the provision that authorizes revocation when a provider or supplier bills for services that it could not have provided on the dates in question. CMS did not dispute that Velocity had provided the services in question, and the ALJ acknowledged that was not an issue. *See* DAB CR3849, at 6. Rather, in *Velocity*, CMS revoked the supplier's billing privileges under new revocation authority added to the regulation as subsection 424.535(a)(8)(ii) in 2015. That new subsection authorizes CMS to revoke billing privileges when a provider or supplier engages in a pattern or practice of submitting claims that do not comply with Medicare requirements. *See* 79 Fed. Reg. 72,500, 72,515 (Dec. 5, 2014).[9] Specifically, CMS revoked Velocity's billing privileges because the documentation Velocity submitted for the claims in question did not support a finding that they were medically necessary, a Medicare requirement. Contrary to Petitioner's representation, the ALJ did not reverse the revocation of Velocity's billing privileges because the services had been provided. As indicated above, that was not even an issue in the case. Rather, the ALJ reversed the revocation, because the new basis for revocation did not take effect until February 3, 2015, and, thus, "did not encompass [Velocity's] conduct at the time of Novitas's action." DAB CR3849, at 6.

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[8] At the beginning of the section of her Request for Review we are now addressing, Petitioner cites a Board decision that she suggests held that CMS must establish a pattern of abuse before revoking under section 424.535(a)(8). *See* RR at 5, citing *Louis J. Gaefke, D.P.M.*. That suggestion is incorrect. Attempting to excuse what he characterized as "accidental billing errors," the supplier in *Gaefke* relied on statements in the preamble to section 424.535(a)(8) that the revocation authority is directed at providers and suppliers engaged in "a pattern of improper billing" and is not intended for "isolated occurrences" or "accidental billing errors." *Id.* at 7. The Board rejected Gaefke's reliance on that language, stating, "We . . . agree with the ALJ that the preamble statements Petitioner cites do not bar CMS from revoking the enrollment of a supplier or provider whose incorrect billing falls within the plain language of the regulation." *Id.* at 8 (citations omitted)*; see also Mohammad Nawaz, M.D., & Mohammad Zaim, M.D., PA*, DAB No. 2687, at 7-8 (2016) (rejecting argument that CMS is required to prove a "pattern of abuse" and intent).

[9] The ALJ correctly noted that the amendments "do not change the language that is the basis for the revocation determination in this case." ALJ Decision at 3 n.3.

3. The ALJ correctly rejected Petitioner's argument that the claims submitted were lawful because they were for services provided by a nurse practitioner that were "incident to" her services.

Petitioner argues that she relied on CMS's "incident to" billing policies which, she contended, permitted her to claim Medicare reimbursement for the services provided to her patients by a nurse practitioner while Petitioner was out of the country. RR at 6; Reply at 3-5. Petitioner asserts that the ALJ erroneously rejected that argument when she raised it below. We conclude that the ALJ did not err in concluding that the "incident to" rule did not permit Petitioner to bill for the services furnished by the nurse practitioner during Petitioner's absence.

The regulations allow a physician, in certain circumstances, to bill for Medicare Part B services provided to their patients by auxiliary personnel (another physician or other practitioner) that are "incident to" the billing physician's services. *See* 42 C.F.R. § 410.26(b) ("Medicare Part B Pays for services and supplies incident to the service of a physician (or other practitioner)"). However, the regulations contain a number of requirements that must be met in order for the physician to bill for "incident to" services.

One of these requirements is that the "incident to" services provided by auxiliary personnel must be provided under the direct supervision of the billing physician. At the time the services were furnished, the regulatory section stating this requirement, section 410.26(b)(5) provided as follows:

> Services and supplies must be furnished under the direct supervision of the physician (or other practitioner). The physician (or other practitioner) directly supervising the auxiliary personnel need not be the same physician (or other practitioner) upon whose professional service the incident to service is based.

42 C.F.R. § 410.26(b)(5).[10] The regulations further stated (and still state) that "*[d]irect supervision* means the level of supervision by the physician (or other practitioner) of auxiliary personnel as defined in § 410.32(b)(3)(ii)," 42 C.F.R. § 410.26(a)(2), and section 410.32(b)(3)(ii) defines direct supervision as follows:

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[10] The version of the regulation quoted by Petitioner in her Reply brief contains amended language that took effect January 1, 2016, well after the services here were provided, and, thus, does not apply here. 80 Fed. Reg. 70,886, 71,372 (Nov. 16, 2015). We also note that the last sentence of the version Petitioner quotes states, "However, only the supervising physician (or other practitioner) may bill Medicare for incident to services." Reply at 5. Petitioner's counsel stated during oral argument that this supported Dr. Shah's position that she could bill for the services provided by the nurse practitioner even though Dr. Shah was out of the country and could not provide direct supervision of the nurse practitioner as she furnished the services. Tr. at 37. We disagree. The language quite clearly says that only the physician providing the supervision may bill, whether or not that's the physician treating the patient more broadly. In any event, as we discuss later, the record does not establish that any physician or practitioner provided direct supervision to the nurse practitioner as she furnished the services in question.

> *Direct supervision* in the office setting means the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed.

42 C.F.R. § 410.32(b)(3)(ii).

The ALJ concluded that the services furnished by the nurse practitioner did not qualify as "incident to" services because Petitioner was unavailable to provide the nurse practitioner with the direct supervision required by section 410.26(b)(5). ALJ Decision at 4-5. The ALJ cited a CMS Medicare Learning Network notice that articulated the definition of "direct supervision" that appears in section 410.32(b)(3)(ii) quoted above. *Id.* The ALJ concluded that because the rule required the supervising physician to be present in the office suite, "Petitioner could not have met the 'incident to' billing requirements if she was out of the country at the time the services were furnished." *Id.*

Although she acknowledges she was out of the country when the nurse practitioner furnished the services, Petitioner nonetheless challenges the ALJ's conclusion, arguing that the physical presence of the billing physician – even in the office suite – is not required. Reply at 3-5. Petitioner acknowledges that section 410.26(b) requires that "incident to" services be provided under the "direct supervision of the physician (*or other practitioner*)" and that "[d]irect supervision" as defined in section 410.32(b)(3)(ii) provides that "the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the [incident to] procedure." Reply at 4 (emphasis in Reply). However, Petitioner then argues,

> To read these two Regulations together in a manner which purports to require the "direct supervision" and personal presence of **only** the billing provider is fundamentally wrong. 42 C.F.R. §426.10 [*sic*]expressly recognizes and permits, under subsections (a)(1), (a)(2), (b) and (b)(5), supervision by the physician ***or other practitioner***. [11]

Id. at 5 (emphasis in Reply).

It is not entirely clear whether Petitioner is arguing that the nurse practitioner (i.e., a non-physician "other practitioner") was providing the required supervision or whether she is suggesting that some physician other than herself supervised the nurse practitioner furnishing the services. If the former, the argument is insupportable on its face because under section 410.26(b)(5), the nurse practitioner who furnished the services would be

[11] Petitioner cited 42 C.F.R. § 426.10 but was clearly referring to section 410.26.

the auxiliary personnel and could not supervise herself. *See* 42 C.F.R. § 410.26(a)(1) (defining "auxiliary personnel" as meaning "any individual who is acting under the supervision of a physician (or other practitioner . . . "). If the latter, there is no evidence in the record to support Petitioner's position. Petitioner cites Petitioner Exhibit 20, Petitioner's affidavit. Although Petitioner's brief does not cite any particular statement in the affidavit, we assume she is referring to the following statement:

> On the three day trips, my husband lined up a nurse practitioner from his separate practice to assist me and I lined up primary care providers for coverage in the case of an emergency if the nurse practitioner or the facility needed emergent intervention from the primary care providers for my patients.

P. Ex. 20, at 1, ¶3. This statement asserts only that Petitioner "lined up primary care providers;" it does not state that the covering providers provided the direct supervision of the nurse practitioner required by the regulations (or any kind of supervision for that matter) each time the nurse practitioner furnished the services for which Petitioner improperly billed Medicare.[12] Moreover, the statement on its face indicates the primary care providers were "lined up" only to be available for emergencies, not to be available for all purposes or to actually be present in the facility where and when the nurse practitioner furnished services during Petitioner's absence.[13] This wholly undercuts any inference that the duties of the covering physicians included direct supervision of the nurse practitioner as she furnished the alleged "incident to" services.

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[12] At oral argument, Petitioner's counsel cited Petitioner's affidavit, Petitioner Exhibit 9 and Petitioner Exhibit 16 when asked by a Board Member if he could cite any record evidence that the "coverage" provided by other physicians during Petitioner's absences "included being present when all of the services rendered by the nurse practitioner were given." Tr. at 11. As discussed above, Petitioner's affidavit does not show that the physician coverage included this activity and neither does Petitioner Exhibit 16. Petitioner Exhibit 9, as discussed below, was not admitted into evidence. We note that in other parts of his argument, counsel cited exhibits not admitted by the ALJ. *See* Tr. at 10 (citing Petitioner Exhibits 11A, 11B, 11C, 11D, 11E and 12 as medical records "which establishes [Petitioner's] examination of these patients," on "either the day she left on trips or after she returned"). Of course, whether Petitioner examined the patients at these limited times is irrelevant since she does not deny being out of the country on the remaining dates when the nurse practitioner provided the services billed under Petitioner's billing number.

[13] We find no evidence that Petitioner made before the ALJ (or in her Request for Review) the argument made in her Reply and at oral argument that a covering physician or other practitioner provided direct supervision to the nurse practitioner as she furnished each of the multiple services in question. When a Board Member asked Petitioner's counsel during oral argument to cite any such evidence, Petitioner's counsel cited only statements in briefs that addressed arrangements for "physician coverage if necessary," not arrangements for supervision of the nurse practitioner. Tr. at 39. Petitioner is not permitted to raise on appeal an issue she could have raised but did not raise before the ALJ or in her Request for Review. *Guidelines, supra,* Completion of the Review Process (a).

Petitioner also cites Petitioner Exhibit 9, but the ALJ did not admit that exhibit to the record. *See* ALJ Decision at 2 (admitting Petitioner Exhibits 1-7; 16-17; and 20; excluding the remainder of Petitioner's exhibits; and admitting CMS Exhibits 1-11). As we discuss later, Petitioner argues that the ALJ erred in excluding under 42 C.F.R. § 498.86 evidence she had not presented during reconsideration.[14] However, Petitioner does not identify Petitioner Exhibit 9 as one of the exhibits improperly excluded by the ALJ. In any event, Petitioner Exhibit 9 merely contains copies of text messages that, like Petitioner's affidavit, show at most that Petitioner made some arrangements for covering physicians during some of her absences, not that she arranged for a physician or other practitioner to provide direct supervision to the nurse practitioner as she furnished services.[15]

A statement in Petitioner's Motion for Summary Judgment also undercuts any inference that the covering physicians supervised the nurse practitioner while she furnished services to Petitioner's patients. *See* Petitioner's Motion for Summary Judgment at unnumbered 7, 9, 12-13 ("On the few dates where Dr. Shah could not be present, she had supporting coverage by three physicians, which were Dr. Jalil Khan, Dr. Sumit Kumar, & Dr. Maulshree Singh. [citation to unadmitted Petitioner Exhibit 9 omitted]. However, CMS has no evidence to suggest that this necessity arose on the dates in question."). If, as this statement says, the covering physicians were not even called upon during Petitioner's absences, they clearly were not providing the direct supervision of the nurse practitioner required for "incident to" services.

Another requirement for "incident to" services is that the "[s]ervices and supplies must be furnished in a noninstitutional setting to noninstitutional patients." 42 C.F.R. § 410.26(b)(1). A "*[n]oninstitutional setting* "means all settings other than a hospital or skilled nursing facility." 42 C.F.R. § 410.26(a)(5). While the ALJ based his rejection of Petitioner's "incident to" argument, as discussed above, on Petitioner's not meeting the requirements of section 410.26(b)(5), section 410.26(b)(1) raises further questions about how the services which Petitioner asserted throughout were provided in nursing homes,

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[14] In a footnote in her Reply, Petitioner moves alternatively for admission of all evidence excluded by the ALJ. Reply at 15 n.2. While Petitioner claims all of the evidence is "'relevant and material' to the issues herein," she makes no argument to support that assertion. Having found no error in the ALJ's handling of Petitioner's submissions, we have no basis for granting this motion and deny it.

[15] At oral argument, Tr. at 11, Petitioner's counsel also cited Petitioner's affidavit and unadmitted Petitioner Exhibit 9 as evidence of direct supervision by the covering physicians, which they are not. Counsel also cited Petitioner Exhibit 16 (Lamar Blount affidavit), but that exhibit as well states only that Petitioner arranged for primary care physician services to be available as needed during her absence, not that she arranged for the covering physicians to provide direct supervision to the nurse practitioner as she furnished services during Petitioner's absence. P. Ex. 16, at 7. Counsel relied during his argument on a number of other exhibits (additional to Petitioner Exhibit 9) that are not in the record because the ALJ excluded them. Tr. at 10 (citing Petitioner Exhibits 11A, 11B, 11C, 11D, 11E and 12).

rather than in an office setting, could be determined to have been properly billed as "incident to" services. Petitioner failed to explain before us how these services could meet the requirement of a noninstitutional setting. The billing data of record indicates that many of the claims submitted to Medicare were for services to patients in skilled nursing facilities (SNFs), which are institutional settings. CMS Ex. 8, at 21-23. Also, in her summary judgment motion, Petitioner stated that she was "treating and billing for seeing patients solely in NF[s] and SNF[s]." Petitioner's Motion for Summary Judgment at unnumbered 9. Finally, in response to questions at oral argument regarding the record references to the type of facility in which the nurse practitioner's services were provided, Petitioner's counsel admitted that the services were provided to residents in nursing facilities that had skilled care components. Tr. at 21-25. Nursing facilities whose services include skilled care services are institutional settings for purposes of section 410.26(b)(1). Thus, by Petitioner's own admission, at least some of the services furnished by the nurse practitioner, and for which Petitioner was found to have improperly billed, were services to patients in institutional settings and, for that reason as well, would not qualify as "incident to" services regardless of whether the direct supervision requirement was met.[16]

B. <u>Petitioner's other arguments have no merit</u>

1. The ALJ committed no abuse of discretion or error in his handling of Petitioner's evidentiary submissions.

Petitioner argues that the ALJ abused his discretion in failing to find good cause for Petitioner to supplement during the ALJ proceeding the evidence she presented to Novitas with her reconsideration request. RR at 9-10. Petitioner also argues that the ALJ erred in excluding Petitioner Exhibits 7 and 8 "as both exhibits are testimonial in nature and relevant to the case." RR at 12. There is no merit to either argument.

The ALJ excluded Petitioner Exhibits 8-9, 10(a)-10(o), 11(a)-11(e), 12-15, 18-19 and 20(a) on the ground Petitioner had not submitted these exhibits with her request for reconsideration and had not shown good cause for submitting them for the first time at the ALJ level. ALJ Decision at 2-3. The ALJ relied on 42 C.F.R. § 498.56(e)(1) which provides that, in provider and supplier appeals, "the ALJ will examine any new documentary evidence submitted to the ALJ by a provider or supplier to determine whether the provider or supplier has good cause for submitting the evidence for the first

[16] The fact that the ALJ did not address section 410.26(b)(1) does not preclude also relying on the latter for our decision since Petitioner herself raised section 410.26 as a defense to the revocation and, in addressing that defense, we must correctly apply the "incident to" regulation as a whole. In any event, as discussed below, we also agree with the ALJ's reason for rejecting this defense.

time at the ALJ level" and that "[i]f the ALJ determines that there was not good cause for submitting the evidence for the first time at the ALJ level, the ALJ must exclude the evidence from the proceeding and may not consider it in reaching a decision." The ALJ found that Petitioner had not shown "good cause." *Id.* at 3.

Petitioner argues that the initial determination letter "fail[ed] to adequately inform her regarding the need to submit all new evidence at the reconsideration level or else she will be completely barred from submitting such evidence at a later date." RR at 15. After advising Petitioner of her right to seek reconsideration of the initial determination, Novitas's letter stated, "You may submit additional information with the reconsideration that you believe may have a bearing on the decision." CMS Ex. 7, at 2. Petitioner appears to be arguing, as she did below, that the phrase "may submit" was ambiguous and did not adequately inform her that it was mandatory to submit at the reconsideration level any additional evidence she wanted considered. *See* ALJ Decision at 3. Petitioner argues that the alleged ambiguity and inadequate information was a violation of due process as well as a basis for the ALJ to find good cause. RR at 15-16. Petitioner also argues that she "was not aware of the necessity for submission of medical records because during the operative time period, Petitioner had not yet received a copy of the Kirk report" and did not have "knowledge that none of [her] medical records were analyzed until the document exchange and the response to public records [FOIA] request was received."[17] RR at 9-10.

We find no abuse of discretion or error of law in the ALJ's decision to exclude the documentary evidence for failure to show "good cause" why that evidence was being submitted for the first time in the ALJ proceeding. Section 498.56(e)(1), as the ALJ noted, "is unambiguous." Without a specific showing of "good cause," required by that regulation, the ALJ was required to exclude the evidence. The ALJ, as he indicated, had no discretion to decline to follow that mandate even if use of the word "may" in the notice of Petitioner's right to seek reconsideration "is ambiguous" with respect to the submission of additional evidence. ALJ Decision at 3. The regulation itself provided adequate notice of the requirement to provide all documents on reconsideration, and Petitioner has not explained why she could not have complied, especially since she was represented by counsel who, as the ALJ noted, was "charged with the responsibility of reading and understanding governing regulations [and] should have known what her responsibilities were" under section 498.56(e)(1). *Id.*

[17] The record does not contain information about a FOIA request, and Petitioner does not explain this assertion.

The ALJ Decision does not specifically discuss Petitioner's assertion that good cause also existed because she "was not aware of the necessity for submission of medical records" until after we received the Kirk affidavit.[18] RR at 9. However, the ALJ concluded that "none of the exhibits that Petitioner offers – including those that I exclude – establishes facts that contradict the undisputed facts upon which I base this decision." ALJ Decision at 3. Accordingly, it is clear that the ALJ viewed the exhibits, even had they been admissible, as irrelevant or immaterial or both. We agree with the ALJ.

Petitioner suggests on appeal that the medical records are relevant because they "show her ongoing involvement with patient care and initial comprehensive work ups – facts which apparently are not in dispute given CMS Response to Petitioner's Motion for Summary Judgment and lack of evidence regarding same." RR at 10 (citations omitted). Petitioner's initial or ongoing involvement with her patients is not relevant because she admitted that whatever involvement she had did not include being present, or even in the country, each time the nurse practitioner furnished the services at issue. Irrelevant for the same reason is the assertion by Petitioner's counsel (citing exhibits not admitted by the ALJ, we note) at oral argument that medical records "establish[] [Petitioner's] examination of these patients," on "either the day she left on trips or after she returned." Tr. at 10 (citing unadmitted Petitioner Exhibits 11A, 11B, 11C, 11D, 11E and 12).

We also find no merit to Petitioner's assertion that the ALJ erred in not admitting Petitioner Exhibits 7 and 8. Petitioner says these exhibits were testimonial in nature and cites *Modesto Radiology Imaging, Inc*., DAB CR3483, at 2 (2014) as holding that "[t]estimonial evidence is not subject to 42 C.F.R. § 405.1028, and, as such, must only be relevant to be admitted." RR at 12. As we stated earlier, ALJ decisions do not bind other ALJs or the Board. In any event, *Modesto* did not discuss the regulation Petitioner cites, which applies to Medicare Part B appeals, not to ALJ review of revocations under Part 498. The decision does not support Petitioner for another reason. The ALJ in *Modesto* admitted an affidavit by the supplier's (an IDTF) coding specialist, finding that it was testimony and not documentary evidence. The ALJ cited *Arkady B. Stern, M.D*., DAB No. 2329, at 4 n.4 (2010) in which the Board observed that "[t]estimonial evidence that is submitted in written form in lieu of live in-person testimony is not 'documentary evidence' within the meaning of 42 C.F.R. § 498.56(e)." However, Petitioner here did not identify either Petitioner Exhibit 7 or Petitioner Exhibit 8 as testimonial evidence being "submitted in written form in lieu of live in-person testimony." Indeed, on her witness list, Petitioner expressly stated, "At this time, Petitioner anticipates introducing no[] statements in lieu of testimony." Petitioner's Exhibit and Witness List at 10. In addition, whether testimonial in nature or not (and on their face they do not appear to be),

[18] Petitioner made this argument below in Petitioner's Reply to CMS' Response to Petitioner's Challenge to Evidence and Witnesses and Objection to Petitioner's New Evidence at 5.

neither the text messages in Petitioner Exhibit 7 nor the letters of recommendation from other practitioners and patients in Petitioner Exhibit 8, have any relevance to our decision which is based on the undisputed material facts, including Petitioner's own admissions, that Petitioner billed Medicare for services furnished to patients while she was out of the country.

In sum, we find no abuse of discretion or error in the ALJ's handling of Petitioner's evidentiary submissions.

2. Petitioner's constitutional challenges cannot be resolved in this forum, and the Board is not authorized to provide equitable relief.

Petitioner makes a number of arguments alleging abridgment of her constitutional rights: 1) that the revocation of her Medicare billing privileges was an unconstitutional abridgment of valuable property (RR at 17); 2) that the ALJ's refusal to review Novitas's rejection of Petitioner's corrective action plan was a denial of due process (RR at 17-18); 3) that initiating revocation proceedings while a criminal prosecution was pending denied her due process and "could violate the Fifth Amendment" (RR at 16-17); and, 4) that the severity of the revocation was disproportionate to the wrongful act she committed (RR 18-19). The Board may not resolve any of these issues.

ALJs and the Board are bound by the regulations and may not declare them unconstitutional or decline to follow them on that basis. *E.g. Fady Fayad, M.D.*, DAB No. 2266, at 14 (2009), *aff'd*, *Fayad v. Sebelius*, 803 F. Supp. 2d 699 (E.D. Mich. 2011). Section 424.535 of the provider and supplier enrollment regulations (42 C.F.R. Part 424, subpart P) specifies the reasons for which CMS may legally revoke a provider or supplier's billing privileges. So long as an ALJ (and the Board) finds that CMS has shown that one of the regulatory bases for enrollment exists, the Board may not refuse to apply the regulation and must uphold the revocation. *E.g. Stanley Beekman, D.P.M.*, DAB No. 2650, at 10 (2015) (stating that an ALJ and the Board must sustain a revocation "[i]f the record establishes that the regulatory elements are satisfied"); *Letantia Bussell, M.D.*, DAB No. 2196, at 13 (2008) (stating that the only issue before an ALJ and the Board in enrollment cases is whether CMS has established a "legal basis for its actions."); *see also id.* at 13 (explaining that "the right to review of CMS' determination by an ALJ serves to determine whether CMS had the authority to revoke [a Petitioner's] Medicare billing privileges, not to substitute the ALJ's discretion about whether to revoke").

Moreover, the Board has emphasized that with respect to appeals under Part 498, ALJs and the Board may only review issues specifically identified as appealable administrative actions (i.e., "initial determinations") in section 498.3(b). *E.g. Vijendra Dave, M.D.*, DAB No. 2672, at 10-11 (2016). Thus, the Board has held that CMS's rejection of a corrective action plan is not subject to review because section 498.3(b) does not identify it as an appealable issue. *DMS Imaging, Inc.*, DAB No. 2313, at 5-6 (2010); *Conchita Jackson, M.D.*, DAB No. 2495, at 6 (2013). For the same reason, the Board held in *Vijendra Dave* that CMS's determination of the length of the reenrollment bar under section 498.535(c) is not subject to review. DAB No. 2672, at 10-11.[19] The Board explained

> Although the re-enrollment bar is a direct and legally mandated consequence of an appealable revocation determination, nothing in Part 498 authorizes the Board to review the length of the bar despite that relationship between a revocation and a reenrollment bar. Given section 498.3(b)'s precise and exclusive enumeration of appealable determinations, we cannot find a CMS action to be appealable under Part 498 unless section 498.3(b) describes the subject matter of that action. *See North Ridge Care Ctr.*, DAB No. 1857, at 8 (2002) (stating that "[b]y its very terms, Part 498 provides appeal rights *only for these listed actions*" (italics added)). On its face, section 498.3(b) does not describe any matter related to a post-revocation re-enrollment bar.

Id. at 10.

Petitioner argued in her briefs and at oral argument that the three-year reenrollment bar is too severe, has caused her financial hardship and should be reduced. RR at 18-19; Reply at 16; Tr. at 27-28. However, as the decisions cited above indicate, the Board is not authorized to reduce the term of the bar. Furthermore, the Board has consistently held that it may not provide equitable relief. *E.g. Arkansas Dep't of Human Servs.*, DAB No. 2664, at 4 (2015) (citations omitted).

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[19] Section 424.535(c) states "[if] a . . . supplier has [his] billing privileges revoked, [he] [is] barred from participating in the Medicare program from the date of the revocation until the end of the re-enrollment bar." That provision further states that the re-enrollment bar "lasts a minimum of 1 year, but not greater than 3 years, depending on the severity of the basis for revocation." *Id.* § 424.535(c)(1).

Conclusion

For the reasons stated 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/

Christopher S. Randolph

/s/

Leslie A. Sussan

/s/

Sheila Ann Hegy
Presiding Board Member