Department of Health and Human Services DEPARTMENTAL APPEALS BOARD Appellate Division

Urology Group of NJ, LLC Docket No. A-17-115 Decision No. 2860 March 23, 2018

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Urology Group of NJ, LLC (Petitioner) appeals a decision by an Administrative Law Judge (ALJ) upholding on the written record the determination of the Centers for Medicare & Medicaid Services (CMS) that the proper effective date for reactivation of Petitioner's Medicare billing privileges was April 28, 2016. *Urology Group of NJ, LLC*, DAB CR4878 (2017) (ALJ Decision).

For the reasons explained below, we conclude that the applicable regulations compel the effective date the ALJ affirmed, based on the date Petitioner filed the Medicare enrollment application to reactivate its billing privileges that CMS approved. Therefore, Petitioner's arguments do not permit the ALJ or the Board to set any earlier date. We therefore affirm the ALJ Decision.

Legal Background

The Medicare program provides health insurance benefits to persons 65 years and older and to certain disabled persons. Social Security Act (Act) §§ 1811, 1833.¹ The Medicare program is administered by CMS, which in turn delegates certain program functions to private contractors. *Id.* §§ 1816, 1842, 1874A; 42 C.F.R. § 421.5(b).

A supplier of Medicare services (which includes physicians and physician practices) must be enrolled in the Medicare program and maintain active enrollment status in order to receive payment for items and services covered by Medicare. 42 C.F.R. §§ 424.500, 424.502, 424.505, 424.510, 424.516. "Enrollment" is the process that CMS uses to

¹ The current version of the Act can be found at <u>https://www.ssa.gov/OP_Home/ssact/ssact-toc.htm.</u> Each section of the Act on that website contains a reference to the corresponding United States Code chapter and section. Also, a cross-reference table for the Act and the United States Code can be found at <u>https://www.ssa.gov/OP_Home/comp2/G-APP-H.html</u>.

(1) identify the prospective supplier; (2) validate the supplier's eligibility to provide items or services to Medicare beneficiaries; (3) identify and confirm a supplier's owners and "practice location(s)"; and (4) grant the supplier "Medicare billing privileges." *Id.* § 424.502.

CMS may deactivate the Medicare billing privileges of a provider or supplier if the provider or supplier does not report a change to the information supplied on the enrollment application within 90 calendar days of when the change occurred. 42 C.F.R. § 424.540(a)(3). If deactivated, a provider or supplier may reactivate billing privileges by meeting certain regulatory and CMS policy benchmarks. In order to reactivate billing privileges, the provider or supplier must generally complete and submit a new enrollment application; or, when deemed appropriate, the provider or supplier may be permitted to simply recertify that the enrollment information currently on file with Medicare is correct. *Id.* § 424.540(b).

When a Medicare enrollment application is approved, CMS (or the Medicare contractor) sets the "effective date for billing privileges" in accordance with 42 C.F.R. § 424.520(d). That provision states that the effective date of a physician's or physician organization's Medicare billing privileges is "the later of . . . [t]he date of filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor" or "[t]he date that the supplier first began furnishing services at a new practice location."²

The determination of a supplier's effective date under section 424.520(d) is an "initial determination" subject to administrative review under 42 C.F.R. Part 498. 42 C.F.R. § 498.3(a)(1), (b)(15); *Victor Alvarez, M.D.*, DAB No. 2325, at 3 (2010). A supplier dissatisfied with a hearing decision issued by an ALJ may request Departmental Appeals Board review of the ALJ Decision. 42 C.F.R. § 498.5(f).

Case Background³

Petitioner is a medical group located in New Jersey. CMS Ex. 1, at 2. In December 2015, Novitas Solutions, Inc. (Novitas), a CMS contractor, learned from a monthly file from the Social Security Administration that one of Petitioner's owners, Dr. Yitzhak Berger, died on October 18, 2015. *Id.*; CMS Ex. 2, at 3. Novitas mailed a letter, dated

² In the preamble to the rulemaking that adopted section 424.520, CMS explained that the term "date of filing" means "the date that the Medicare contractor receives a signed . . . enrollment application that the Medicare contractor is able to process to approval." 73 Fed. Reg. 69,726, 69,766-69 (Nov. 19, 2008). The Board has applied that interpretation in resolving disputes concerning the effective date of a supplier's enrollment. *See Alexander C. Gatzimos, MD, JD, LLC,* DAB No. 2730, at 4 (2016).

³ The factual information in this section is drawn from the ALJ Decision and the record and is presented to provide a context for the discussion of the issues raised on appeal. Nothing in this section is intended to replace, modify, or supplement the ALJ's findings of fact.

December 9, 2015, to the address on file for Petitioner, requesting that Petitioner submit a CMS-855B change request to update its enrollment record by removing Dr. Berger as an owner. CMS Ex. 3, at 1. The letter also informed Petitioner that it must submit the change request "within 90 calendar days of the date of [the] letter in order to avoid deactivation of Medicare billing privileges." *Id.* Petitioner failed to respond to Novitas' December 9, 2015 letter. CMS Ex. 1, at 3.

Novitas sent another letter, dated April 5, 2016, to the address on file for Petitioner stating that Petitioner's Medicare billing privileges were "deactivated as of April 5, 2016, due to the fact that Novitas did not receive the CMS 855B change request to delete Yitzhak Berger as a partner as requested on December 9, 2015, within the allotted 90 calendar days."⁴ CMS Ex. 4, at 1. On April 28, 2016, CMS received Petitioner's Form CMS-855B enrollment application that deleted five partners from Petitioner's Medicare enrollment record, including Dr. Yitzhak Berger. CMS Ex. 5.

By letter dated May 10, 2016,⁵ Novitas informed Petitioner that its reactivation enrollment application had been approved, and issued Petitioner a new Provider Transaction Access Number (PTAN). CMS Ex 6, at 1. Novitas set the effective date for reactivation as April 28, 2016, the date that Novitas received Petitioner's Form CMS-855B. *Id.* at 2.

In a letter dated June 14, 2016, Petitioner requested reconsideration of the effective date for reactivation, arguing that the effective date should be the date of deactivation, so as not to create a "gap" in billing privileges. CMS Ex. 2. Petitioner claimed that it did not receive either the December 9, 2015 letter requesting that Petitioner update its enrollment information or the April 5, 2016 deactivation letter. *Id.* at 3, 4. Petitioner presumed that the effective date was assigned based on instructions in the Medicare Program Integrity Manual (MPIM) to use the date of the contractor's receipt of the reactivation application. *Id.* at 4, citing MPIM, Pub. No. 100-08, ch. 15, § 15.27.1.2. Petitioner argues that the manual instruction contradicts the language of 42 C.F.R. § 424.540(c), which states that "the deactivation of Medicare billing privileges does not have any effect on a provider or supplier's participation agreement." *Id.* at 5-9.

⁴ The April 5, 2016 deactivation letter did not cite a specific regulatory authority for deactivation. CMS Ex. 4. The December 9, 2015 letter requesting information from Petitioner and the May 10, 2016 reactivation letter both cited to 42 C.F.R. § 424.540(a)(2) as the basis for deactivation. CMS Ex. 3, at 1; CMS Ex 6, at 1.

⁵ Novitas sent a corrected reactivation letter to Petitioner, dated May 16, 2016, which added a delegated official. CMS Ex. 6, at 6-10.

CMS issued an unfavorable Reconsideration Determination by letter dated July 28, 2016. CMS Ex. 7. The Reconsideration Decision stated in relevant part:

Urology Group of NJ LLC has not provided evidence to support an earlier effective date. Therefore, Novitas Solutions is not granting you access to the Medicare Trust Fund (by way or issuance) of a new Medicare effective date. The Medicare Participating Physician or Supplier Agreement (participation agreement) effective date was not affected by the deactivation of billing privileges; therefore, a new Medicare Participating Physician or Supplier Agreement (form CMS-460) was not required upon reactivation of the billing privileges for Urology Group of NJ LLC. There is no documentation to show that Novitas Solutions received a reactivation application prior to April 28, 2016 to receive an earlier effective date. Therefore, the effective date of Medicare billing privileges of April 28, 2016 for the new reactivation PTAN 489888 was provided and set up correctly based on the reactivation regulations stated above.

Reconsideration Determination at 3.

On August 2, 2016, Petitioner requested an evidentiary hearing before an ALJ, reiterating the arguments made in the Request for Reconsideration. Request for Hearing. CMS filed a pre-hearing brief and motion for summary judgment on September 20, 2016, asserting that there were no disputes of material fact and that the effective date was lawful under sections 424.520(d) and 424.540. Petitioner filed its pre-hearing brief (P. Br.) in opposition on October 26, 2016.⁶ Petitioner reiterated its arguments and asserted that Novitas "did not fully conform to CMS's enrollment effective date rules that allow payment for services for the thirty-day period prior to the date that the contractor received Petitioner's application to reactive its billing privileges." P. Br. at 2.

ALJ Decision

On July 5, 2017, the ALJ issued a decision based on the written record affirming CMS's determination of an April 28, 2016 effective date for the reactivation of Petitioner's Medicare billing privileges. First, the ALJ analyzed the rulemaking history for the relevant regulations, concluding in relevant part:

⁶ CMS filed eight exhibits with its pre-hearing brief, and Petitioner filed nine exhibits with its pre-hearing brief. These were entered into evidence by the ALJ and are designated as CMS Exs. 1-8, and P. Exs. 1-9, respectively. ALJ Decision at 3.

Although section 424.540(a)(3) indicates that the deactivation does not have any effect on the supplier's participation agreement or conditions of participation, deactivation nonetheless may cause "adverse consequences," most significantly, the loss of billing privileges. The effective date of reactivation of billing privileges is governed by 42 C.F.R. § 424.520, "Effective date of Medicare billing privileges," which states, in pertinent part, that the effective date for billing privileges, as applicable to this case, is "[t]he date of filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor." 42 C.F.R. § 424.520(d)(1). The July 28, 2016 reconsidered determination was consistent with 42 C.F.R. § 424.520(d) in its determination that the effective date of Petitioner's reactivated billing privileges was correctly determined to be April 28, 2016. CMS Ex. 7 at 2. Novitas correctly applied section 424.520(d), and an effective date earlier than April 28, 2016 is not warranted. CMS Ex. 7 at 2.

ALJ Decision at 7. The ALJ then rejected Petitioner's argument that the MPIM provisions contradict the controlling Medicare statute and regulations. Citing to the Board's decision in *Willie Goffney, Jr., M.D.*, DAB No. 2763 (2017), *appeal docketed*, No. 2:17-cv-08032-MRW (C.D. Cal. Nov. 3, 2017), the ALJ concluded that "the relevant regulations, 42 C.F.R. §§ 424.520(d)(1) and 424.540(c), are dispositive" and that she did not need to rely on the "sub-regulatory CMS policies" to reach a conclusion that "the effective date of Petitioner's reactivated billing privileges should be the date Petitioner submitted the Medicare enrollment application that served to reactivate its billing privileges." ALJ Decision at 8, 9.

The ALJ next rejected Petitioner's argument that the lapse in Petitioner's billing privileges contradicted section 424.540(c)'s provision that the deactivation of billing privileges "does not have any effect" on a deactivated supplier's "participation agreement or any conditions of participation." 42 C.F.R. § 424.540(c); ALJ Decision at 9-10. The ALJ noted that a supplier's participation agreement is triggered by the submission of Form CMS-460 (which, as the quoted language from the Reconsideration Determination above made clear, was not interrupted by the deactivation). ALJ Decision at 10. The ALJ concluded, however, that "nothing in the language on the face of a Form CMS-460 binds CMS or its contractors to reimburse the . . . supplier for every service provided to a Medicare beneficiary." *Id.* Hence, the ALJ did not agree with Petitioner that the fact that a gap may arise in billing privileges depending on when a deactivated supplier files an application to reactivate implies a conflict with section 424.540(c). *Id.*; Request for Hearing at 4.

The ALJ also rejected Petitioner's argument that it never received the December 9, 2015 and April 5, 2016 letters from Novitas, concluding that "Petitioner's allegations that it has been unable to locate either letter are insufficient to rebut the presumption that Novitas mailed each letter to the address listed on the letter." ALJ Decision at 10. Finally, the ALJ rejected Petitioner's argument that Novitas should have granted Petitioner a 30-day retrospective billing period pursuant to section 424.521(a)(1). *Id.* at 10-11. The ALJ concluded that, "[a]s Petitioner has not asserted that it was precluded from submitting the updated enrollment application prior to rendering services in the six months following the death of one of its owners, I see no basis to consider whether CMS or its contractor should have exercised discretion to grant a 30-day retrospective billing period in accordance with section 424.521(a)(1)." *Id.*

Standard of Review

We review a disputed finding of fact to determine whether the finding is supported by substantial evidence, and a disputed conclusion of law to determine whether it is erroneous. *Guidelines – Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's or Supplier's Enrollment in the Medicare Program*, accessible at http://www.hhs.gov/about/agencies/dab/different-appeals-at-dab/appeals-to-board/guidelines/index.html?language=en.

<u>Analysis</u>

I. We review only Petitioner's reactivation effective date in this proceeding.

The governing regulations grant providers and suppliers the right to appeal certain specified "initial determinations" by CMS for ALJ and Board review, which the Board has held include initial determinations regarding the effective date of Medicare billing privileges. *Alvarez* at 3; 42 C.F.R. §§ 498.5(1) and 498.3(b)(15). The regulations do not grant suppliers the right to appeal deactivations. *Goffney* at 5. Rather, suppliers are afforded the opportunity to file a "rebuttal" to the contractor, which is "not itself an appeal." *Id.*; 42 C.F.R. §§ 424.545(b) and 405.374. Thus, our authority in this case extends only to review the April 28, 2016 effective date for the reactivation of Petitioner's Medicare billing privileges established in the July 28, 2016 reconsidered determination and affirmed by the ALJ.

Petitioner's underlying concern in this case appears to be the reimbursement for services rendered in the three week "gap period" between the effective dates for the deactivation and reactivation of Petitioner's Medicare billing privileges. Petitioner makes several arguments in this vein, including: (1) The deactivation regulations, as promulgated in 2006, do not authorize a "gap period" for the reimbursement of covered services; (2) a

valid participation agreement binds CMS to reimburse a supplier for services rendered during the deactivation period; and (3) CMS's refusal to retroactively reimburse a supplier for services rendered during the deactivation period without the opportunity to appeal constitutes a deprivation of property without due process. These arguments, to the extent that they seek Medicare claim reimbursement, "are not cognizable in <u>this</u> forum" and "may be appealed only after submitting a claim and only through the process set out in 42 C.F.R. Part 405." *Goffney* at 6; *Vijendra Dave, M.D.*, DAB No. 2672, at 12 (2016). We therefore review the merits of these arguments only to the extent that they inform our understanding of the authority governing the effective date of reactivations.

Petitioner also argues that the ALJ erred in her conclusion that evidence presented by Petitioner was insufficient to rebut the presumption that Petitioner received both the December 9, 2015 letter from Novitas providing notice of its intent to deactivate Petitioner's billing privileges and the April 5, 2016 deactivation letter. Request for Review (R.R.) at 18-19. We need not address this argument, as whether or not Petitioner was notified of the deactivation of its Medicare billing privileges is outside the Board's authority to review. Petitioner's Medicare billing privileges were deactivated beginning April 5, 2016, a fact that is supported by the evidence. CMS Ex. 4, at 1. Petitioner may not now challenge the effectuation of the deactivation through an appeal that solely concerns the effective date of reactivation.

II. The governing authority to determine the effective date for reactivation of *Petitioner's Medicare billing privileges is 42 C.F.R. § 424.520(d).*

The Board has held, on several occasions, that the policy of CMS to apply the regulation found at 42 C.F.R. § 424.520(d) to determine the effective date for the reactivation of Medicare billing privileges is proper. *See, e.g., Goffney* at 7; *Arkady B. Stern*, DAB No. 2329, at 4 (2010). Petitioner claims, however, that the Board has not previously contemplated the statutory construction and constitutional arguments presented in Petitioner's appeal, and should therefore reconsider its deference to the agency's interpretation in this matter.

The Board has explained its role in determining whether deference to an agency's interpretation of its own regulations is appropriate in the following way:

As an administrative adjudicative body, in conducting our review, we are bound by all applicable laws and regulations. Where the applicable law is clear, we apply it by its terms. When it is silent or ambiguous, we must determine how to appropriately interpret and apply it. We do not undertake to develop our own interpretation in a vacuum, however. A program agency's interpretation of a statute that it is responsible for implementing and of the regulations that the agency has issued is entitled to deference as long as the interpretation is reasonable and the nonfederal party had timely and adequate notice of that interpretation or did not rely to its detriment on another reasonable interpretation. *Blackfeet Tribe*, DAB No. 2675, at 11 (2016), citing *Missouri Dep't of Soc. Servs.*, DAB No. 2184, at 2 (2008). Deference to an agency interpretation is especially appropriate where the interpretation has been a consistent one predating the litigation in which the agency is seeking to apply it.

Orton Motor Co., d/b/a Orton's Bagley, DAB No. 2717, at 6 (2016), aff'd, Orton Motor, Inc., D/B/A Orton's Bagley v. U.S. Dep't of Health and Human Servs., No. 16-1299, 2018 WL 1386141 (D.C. Cir. Mar. 20, 2018). While this summary appears in a case relating to tobacco enforcement, the principles expressed apply equally here.

Using this framework, we first look to whether the statute or implementing regulations speak clearly to the issue at hand. The regulations unambiguously state that, in order for a supplier that is deactivated for any reason other than non-submission of a claim to reactivate its Medicare billing privileges, it must submit a new enrollment application or, when deemed appropriate, recertify that the enrollment information currently on file with Medicare is correct. 42 C.F.R. § 424.540(b)(1). Petitioner argues that the regulations are silent, however, regarding the establishment of the reactivation effective date. R.R. at 4. The only provision in the regulations concerning the effective date for Medicare billing privileges in general provides as follows:

424.520 Effective date of Medicare billing privileges

* * *

(d) *Physicians, nonphysician practitioners, and physician and nonphysician practitioner organizations.* The effective date for billing privileges for... physician...organizations is the later of the date of filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor or the date an enrolled physician . . . first began furnishing services at a new practice location.

42 C.F.R. § 424.520(d). Petitioner asserts that section 424.520(d) only applies to initial determinations, not reactivations. R.R. at 9-11. Petitioner cites to the 2008 final rule promulgating the provisions in section 424.520(d), noting that the preamble included a discussion regarding the approaches CMS considered for establishing "the initial enrollment date" for physicians and nonphysician practitioners, but was silent regarding

reactivations. *Id.* at 10; 73 Fed. Reg. 69,726, 69,766 (Nov. 19, 2008). Petitioner also claims that it is not "completely logical" to apply section 424.520(d) to reactivations because the "reactivation process has no similarity to the initial enrollment process" other than requiring a supplier to submit an enrollment application. Reply at 6.

As CMS notes, 42 C.F.R. § 424.520(d) is the only regulatory provision that addresses the issue of setting the effective date for Medicare billing privileges. Response at 7. Neither the title of 42 C.F.R. § 424.520(d), "Effective date of Medicare billing privileges," nor the text distinguishes between initial enrollments and reactivations, or limits the scope of the provision to initial enrollments only. Thus, a plain reading of the regulations indicates that the provision applies to all instances in which an effective date for Medicare billing privileges must be set, including reactivations. Moreover, the fact that a supplier must file a new enrollment application in order to reactivate its billing privileges is consistent with the language of section 424.520(d) and compelling evidence that the provision should apply to reactivations. Nonetheless, in light of Petitioner's arguments that the regulations do not explicitly reference the effective date for reactivations, we will proceed to consider whether the agency's interpretation of its own regulations is reasonable, and whether Petitioner has been provided with adequate notice of that interpretation.

A. CMS relied on a reasonable interpretation of the regulations that is consistent with the regulations as a whole and the rulemaking history.

Petitioner's primary argument is that the effective date should be set so that a provider or supplier can collect Medicare payments for services rendered during the period of deactivation. Petitioner states that the original revocation regulations, as promulgated in 2006, "simply created a gap period until the revoked provider or supplier successfully reenrolled in Medicare." R.R. at 5. Petitioner asserts that by setting the reactivation effective date based on when the reactivation enrollment application was received, Petitioner is "in the same position it would have been if it had received a billing privilege revocation . . . in the initial two years in which the billing privilege revocation rules were in effect." *Id.* at 6. Petitioner argues that the deactivation regulations are thus rendered "redundant and superfluous" with the revocation regulations because "there would have been no need for the deactivation regulations at all if it had been CMS's intent to create an enrollment gap based on the reactivation effective date." *Id.* at 4, 5 (emphasis removed). Petitioner asserts, therefore, that CMS intended for deactivations to merely delay, not preclude, a supplier from collecting reimbursement for services rendered during the deactivation period. *Id.* at 8-9.

We find Petitioner's recitation of the rulemaking history to be incomplete and its arguments unavailing. CMS adopted the deactivation and revocation regulations in the April 26, 2006 final rule. 71 Fed. Reg. 20,754 (Apr. 26, 2006). "Deactivate" means that a provider's or supplier's Medicare billing privileges are "stopped, but can be restored upon submission of updated information." 42 C.F.R. § 424.502. In comparison, "revoke" means that a provider or supplier's Medicare billing privileges are "terminated." *Id.* The stated purpose of deactivation actions, which the drafters codified in section 424.540(c), provided that:

Deactivation of Medicare billing privileges is considered a temporary action to protect the provider or supplier from misuse of their billing number and to also protect the Medicare Trust Funds from unnecessary overpayments.

71 Fed. Reg. 20,754, 20,761; 42 C.F.R. § 424.540(c). In addition to regulations governing deactivations and revocations, the 2006 final rule also promulgated regulations governing enrollment requirements and payment liability. 71 Fed. Reg. 20,754. By Petitioner's own admission, "[r]egulations adopted simultaneously must not be interpreted in a manner that renders an entire regulation superfluous, void, or insignificant." R.R. at 6. The regulations, taken together, clearly establish that a deactivated provider or supplier was not intended to be entitled to Medicare reimbursement for services rendered during the period of deactivation.

Prior to the 2006 rulemaking, CMS had already adopted the provision found at section 424.5(a)(2), which states that, as a basis for receiving a Medicare payment, "[t]he services must have been furnished by a provider, nonparticipating hospital, or supplier that was, *at the time it furnished the services*, qualified to have payment made for them." 42 C.F.R. § 424.5(a)(2) (emphasis added). The 2006 final rule prescribed new requirements for Medicare reimbursement eligibility codified at 42 C.F.R. § 424.505, which provides that in order to be eligible to receive payment for services rendered, a provider or supplier must be enrolled in the Medicare program and granted billing privileges. 71 Fed. Reg. 20,754, 20,776.⁷ A provider or supplier without active billing privileges at the time services were furnished would therefore not qualify to receive Medicare payments for such services.

The 2006 final rule also promulgated the provision found at 42 C.F.R. § 424.555, which provides that "[n]o payment may be made for otherwise Medicare covered items or services furnished to a Medicare beneficiary by a provider or supplier if the billing privileges of the provider or supplier are deactivated . . ." and "any expense incurred for

⁷ 42 C.F.R. § 424.505 was amended by a final rule published in 2014. 79 Fed. Reg. 72,531 (Dec. 5, 2014). The basic enrollment requirements referenced above remain unchanged.

such otherwise Medicare covered item or service shall be the responsibility of the provider or supplier." 42 C.F.R. § 424.555. The language of this provision explicitly refutes Petitioner's argument that the drafters intended for a provider or supplier to be able to collect Medicare payments for services rendered during the period of deactivation.

Moreover, section 424.555 is consistent with the language of section 424.5(a)(2), because Medicare will not reimburse a provider or supplier if it was not qualified to have payment made at the time it furnished the services. Hence, logically, the provider or supplier might well incur costs for providing services that would otherwise have been covered by Medicare but remain the responsibility of the deactivated provider or supplier. The payment limitation in section 424.555 is also consistent with section 424.540(c), because it not only protects a provider or supplier from misuse of its billing number, but also protects the Medicare Trust Funds from unnecessary overpayments. Finally, it is consistent with the drafters' stated purpose for the provision at 42 C.F.R. § 424.520(d), that "Medicare will only pay for services furnished by licensed practitioners that meet all of the Medicare program requirements." 73 Fed. Reg. 69,726, 69,767.

We disagree, furthermore, with Petitioner's assertion that it is in the same position it would have been if it had been revoked in the initial two years that the revocation regulations were in effect. R.R. at 5-6. Even before the August 2008 final rule instituted a reenrollment bar for revocations, the effects of a revocation action were more substantial than simply losing active Medicare billing privileges, and differed from the effects of a deactivation action in substantive ways. For instance, revocations were considered final adverse legal actions, and were required to be reported to CMS in the provider or supplier's Medicare enrollment application. See, e.g., Form CMS-855B at 14.8 The regulations also required CMS to automatically review every enrollment file with which a revoked provider or supplier had an association to determine if the revocation warranted an adverse action of an associated provider or supplier. 71 Fed. Reg. 20,754, 20,761; 42 C.F.R. § 424.535(e) (Jun. 20, 2006). Taking these unique effects of revocation into consideration, it is reasonable to conclude that CMS intended for revocations and deactivations to share the feature of precluding a provider or supplier from collecting reimbursement for services rendered during the period of inactive Medicare billing privileges, while simultaneously intending for revocations to have more severe consequences on a provider's or supplier's ability to participate. Thus, given the regulations as a whole and the rulemaking history, we conclude that CMS relied on a reasonable interpretation of the regulations to set Petitioner's reactivation effective date.

⁸ A copy of CMS Form-855B can be accessed at <u>https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/cms855b.pdf</u>.

B. *CMS* provided Petitioner with timely and adequate notice of CMS's interpretation of the regulations regarding reactivation effective dates.

CMS has consistently published its interpretation of the regulations in the MPIM since the adoption of 42 C.F.R. § 424.520(d). The most recent relevant revision, in 2015, instructs contractors to set the effective date for reactivation of billing privileges as the date when the contractor receives a re-enrollment application that it processes to completion, consistent with section 424.520(d). MPIM, CMS Pub. 100-08, ch. 15, § 15.27.1.2 (Rev. 561, effective Mar. 18, 2015). Petitioner asserts that the 2015 MPIM revision was the first time that CMS adopted the policy to apply section 424.520(d) to reactivations, and that no "commentary by CMS of any intent to extend the reach of the newly adopted regulation to set the effective date of billing privileges" had been published. R.R. at 10-11. Petitioner ignores CMS's previous MPIM revisions regarding the reactivation effective dates, beginning with a 2009 revision to chapter 10,⁹ which provided as follows:

Note that for purposes of 42 CFR §424.520(d) and §424.521(a), a CMS-855 reactivation application is treated as an initial enrollment application. This means that a reactivated provider will have a new effective date (i.e., the later of the date of filing or the date it first began furnishing services at a new practice location) and, per §424.521(a), limited ability to bill retrospectively.

MPIM, CMS Pub. 100-08, ch. 10, § 10.6.1.4 (Rev. 289, effective Jan. 1, 2009). CMS also issued a second revision to chapter 10 of the MPIM in 2009, which stated the following:

For physicians,... or organizations (e.g., group practices) consisting of any of the aforementioned categories of individuals, the contractor shall establish the reactivation effective date as the later of: (a) the filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor, or (b) the date the supplier first started furnishing services at a new practice location.

MPIM, CMS Pub. 100-08, ch. 10, § 10.13.1 (Rev. 295, effective July 27, 2009). We therefore conclude that Petitioner had adequate notice of CMS's interpretation of the regulations and should have known the effects of deactivation.

⁹ The provisions contained in chapter 10 of the MPIM were subsequently reorganized and moved to chapter 15. MPIM, CMS Pub. 100-08, ch. 15 (Rev. 295, effective July 27, 2009).

Moreover, even if CMS had failed to provide notice of its interpretation, the Board would nevertheless apply the agency interpretation because Petitioner has not proved that it actually relied on a reasonable alternative interpretation of the regulations. *Cibola General Hosp.*, DAB No. 2387, at 7-8 (2011). In short, even if we had not concluded (as we did) that the plain language of the current regulations directed the effective date set by the contractor, we would not have found Petitioner's arguments to provide any persuasive basis to reject CMS's interpretation and application of the regulations.

C. The existence of a supplier participation agreement does not compel CMS to reimburse Petitioner for services rendered during the period of deactivation.

A supplier participation agreement is effectuated by the submission of Form CMS-460, titled "Medicare Participating Physician or Supplier Agreement."¹⁰ Prospective participants must provide their name, address, and National Provider Identifier (NPI), as well as sign and date the agreement. Form CMS-460, at 1. The agreement is not signed by CMS. *Id.* Petitioner asserts that CMS is bound by this agreement to pay a participating supplier for covered services furnished during any period of deactivation. R.R. at 11-12; Reply at 3-5. Petitioner provides no legal authority to support this claim other than 42 C.F.R. § 424.540(c), which states that "[t]he deactivation of Medicare billing privileges does not have any effect on a provider or supplier's participation agreement or any conditions of participation."

Neither the governing authority nor the language of the participation agreement itself supports Petitioner's interpretation regarding the effects of the agreement. There are no provisions in the regulatory framework that give a participation agreement the authority to bind CMS to payment for services rendered during a period when a participating supplier's billing privileges are deactivated. The Act stipulates that the purpose of a supplier participation agreement is for a supplier to accept payment on an assignment-related basis for all items and services furnished under Medicare. Act § 1842(h)(1). Likewise, the body of the participation agreement provides that the participant

hereby enters into an agreement with the Medicare program to accept assignment of the Medicare Part B payment for all services for which the participant is eligible to accept assignment under the Medicare law and regulations and which are furnished while this agreement is in effect.

¹⁰ The record does not contain a copy of Petitioner's participation agreement with CMS. For the purposes of this discussion, we rely on the content of a generic Form CMS-460. See <u>https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms460.pdf</u>.

Form CMS-460, at 1. CMS also explicitly details the benefits of entering into an agreement in its instructions on Form CMS-460, stating that participants are put on a Medicare fee schedule five percent higher than nonparticipants, receive direct and timely reimbursement, and have "one stop" billing for beneficiaries who have Medigap coverage. *Id.* at 2; *see also* Act § 1848(a)(3). The agreement does not contemplate or impose obligations on CMS beyond providing these stated benefits. Thus, while a deactivated supplier's participation agreement is still active pursuant to 42 C.F.R. § 424.540(c), the effect of that agreement remains the statutorily defined assignment of payment, and not, as Petitioner contends, the expectation of payment for services rendered in the absence of active Medicare billing privileges.

D. Applying 42 C.F.R. § 424.520(d) to set the reactivation effective date does not constitute an unlawful deprivation of property without due process.

The Board may not declare unambiguous statutes or regulations unconstitutional and decline to follow them on that basis. *Saeed A. Bajwa, M.D.*, DAB No. 2799, at 15 (2017), *appeal docketed*, No. 3:17-cv-00792 (GTS-DEP) (N.D.N.Y. July 19, 2017); *Fady Fayad, M.D.*, DAB No. 2266, at 14 (2009), *aff'd, Fayad v. Sebelius*, 803 F. Supp. 2d 699 (E.D. Mich. 2011). The Board may, however, consider a constitutional claim to the extent that it challenges the manner in which a regulation is interpreted or applied in a particular case. *Fayad* at 14, n.10; *Sentinel Medical Laboratories, Inc.*, DAB No. 1762, at 11-12 (2001), *aff'd sub nom., Teitelbaum v. Health Care Financing Admin.*, No. 01-70236 (9th Cir. Mar. 15, 2002), *reh'g denied*, No. 01-70236 (9th Cir. May 22, 2002).

Petitioner attempts to inject a constitutional issue into this straightforward matter by arguing that the consequences of its own failure to abide by requirements of which it was or should have been aware when it chose to participate in Medicare somehow deprive it of property rights to which it claims entitlement without adequate due process. Petitioner asserts that CMS is not entitled to deference because setting the reactivation effective date according to 42 C.F.R. § 424.520(d) creates a "gap period" that results in an unconstitutional permanent deprivation, or taking, of property.¹¹ R.R. at 12-18. We disagree. First, we explained that the loss of billing privileges while deactivated results from the plain language of the regulations, by which we are bound. Second, Petitioner has not shown that CMS's regulation setting the effective date of reactivations according to section 424.520(d) constituted a "taking" of Medicare payments in which Petitioner had a property right. Rather, the ability for Petitioner to bill for Medicare reimbursement rested entirely in Petitioner's own hands. Finally, we reject Petitioner's contention that its analysis of due process rights should alter the reading or application of the deactivation.

¹¹ Petitioner values the Medicare reimbursement for services furnished during the deactivation period at approximately \$821,000. R.R. at 17.

Petitioner argues that case law differentiates between "temporary suspensions" in which a provider can recover later if the basis for suspension proves unfounded, and "permanent actions" in which appeal rights may be required. R.R. at 14, 17, citing inter alia *Clarinda Home Health v. Shalala*, 100 F.3d 526 (8th Cir. 1996) (no hearing rights in suspension of Medicare payments during an ongoing fraud investigation); *Cleanmaster Industries, Inc. v. Shewry*, 491 F. Supp. 2d 937 (C.D. Cal. 2007) (hearing needed before state debarment action against Medi-Cal provider). Petitioner then suggests that, because this distinction was supposedly so clear even before 2006, CMS's deactivation regulation must not have been intended to create a "gap period" without providing hearing rights from deactivation (or should be so interpreted at any rate to preserve its constitutionality). R.R. at 15-16.

The case law on which Petitioner relies demonstrates no such bright line and certainly does not persuade us that the applicable regulations do not mean what we have found that the regulations mean. Petitioner contends that these constitutional rights to appeal permanent actions arise from providers' property interests in program participation. R.R. at 14, citing Patchogue Nursing Ctr. v. Bowen, 797 F.2d 1137, 1144-45 (2d Cir. 1986) ("Health care providers have a constitutionally protected property interest in continued participation in the Medicare and Medicaid programs ..., and are thus entitled to some form of hearing before being finally deprived of that interest."). As to Petitioner specifically, the record does not show that Petitioner ever lost its participation in the Medicare program, as it was not excluded or revoked. What Petitioner actually seeks in this appeal is not to challenge a loss of continued participation in the program but to be compensated for services it chose to provide to Medicare beneficiaries at a time when it had been informed that its billing privileges were deactivated. Petitioner is merely being held to the requirements of the Medicare program which it accepted when it enrolled and of which it was obliged to be aware. See Heckler v. Cmtv. Health Svcs. of Crawford County, Inc., 467 U.S. 51, 64 (1984) ("As a participant in the Medicare program, respondent had a duty to familiarize itself with the legal requirements for cost reimbursement."). Petitioner could have, at any time prior to deactivation, submitted the required information to maintain active billing privileges. Likewise, Petitioner could have reactivated its billing privileges by submitting its enrollment application at any point during the deactivation period, but waited three weeks to do so. Petitioner chose to continue to provide services to Medicare beneficiaries during a period when it knew or should have known it would have no right to bill for any services provided. No taking, either temporary or permanent, has thus occurred.

Other circuits, moreover, have not accepted the Second Circuit's conclusions and would not accept a property interest claim even in participation in the Medicare program. *See*, *e.g., Erickson v. U.S. ex rel. Dept. of Health and Human Servs.*, 67 F.3d 858, 862 (9th Cir. 1995) (Health care providers "do not possess a property interest in continued participation in Medicare, Medicaid, or the federally-funded state health care programs.")

The other cases cited by Petitioner do not support its claims. The court in *Clarinda* did not hold that any administrative action that results in a financial loss triggers a due process right to a hearing, but merely held that the supplier "failed to establish that the temporary suspension of Medicare payments without a hearing is a colorable constitutional claim," and therefore had no right to judicial review absent exhaustion of administrative remedies under section 405(g) of the Act. 100 F.3d at 531. *Cleanmaster* involved a Medi-Cal pharmacy debarred under California's anti-fraud laws. The court recognized that Erickson rejected property interest claims in program participation but noted that *Erickson* did state that a provider's liberty interests might be implicated "where 'a charge impairs [its] reputation for honesty or morality,' 'the accuracy of the charge is contested, there is some public disclosure of the charge, and it is made in connection with the termination of employment or the alteration of some right or status recognized by [] law." 491 F. Supp. 2d at 942, quoting *Erickson*, 67 F.3d at 862. The court found that the charges against Cleanmaster met those criteria and hence required a hearing before debarment. Petitioner has not asserted any liberty interest in these proceedings, nor is there any reason to expect that deactivation (unlike debarment) would impugn a provider's reputation for honesty or morality.

Given Petitioner's failure to demonstrate any procedural due process claims to hearing rights for Medicare participating health care providers beyond those provided by statute and regulation, we cannot accept Petitioner's theory that the deactivation regulations must be re-interpreted in a manner to prevent any adverse financial consequences resulting from deactivation. We therefore conclude that Petitioner's constitutional arguments, to the extent that we may reach them because they are directed to the interpretation of the deactivation regulation rather than the assertion of Petitioner's own due process claims, are unpersuasive.

Conclusion

For the reasons stated above, we affirm the ALJ Decision.

/s/ Christopher S. Randolph

/s/ Constance B. Tobias

/s/

Leslie A. Sussan Presiding Board Member