No. 21-

In The Supreme Court of the United States

WILLIE H. GOFFNEY, JR., M.D., ET AL.,
Petitioners,

v.

XAVIER BECERRA, Secretary of the United States Department of Health and Human Services, in his official capacity,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

Petitioner is a surgeon, practicing medicine for 30 years. In 2008, Medicare stopped paying his claims, allegedly for nonsubmission of claims, but did not tell him why until 2012. The Medicare contractor then told him how to restore his account and obtain payment for overdue claims and he followed those instructions. Yet, the contractor reversed itself and denied his claims based on a unique interpretation of certain regulations. Petitioner contended the unambiguous regulations compelled a different result and sought judicial relief. The court below, however, deferred to HHS's regulatory interpretation and denied Petitioner's claim. The court below also interpreted another HHS regulation in a way that HHS never had, precluding recovery for outstanding claims regardless of the reason. Combined, the result forecloses meaningful judicial review despite protections in 5 U.S.C. § 706 and 42 U.S.C. § 405(g).

The questions presented are:

1. Whether the regulatory deference test set forth in *Auer v. Robbins*, 519 U.S. 452 (1997) and *Kisor v. Wilkie,* --- U.S. ---, 139 S.Ct. 2400 (2019), should be retired to allow courts the ability to interpret administrative regulations without being required to defer to the agency's interpretation.

2. Alternatively, whether the test set forth in *Auer* and *Kisor* should be revised to ensure courts are able to provide meaningful review of an administrative decision that contravenes unambiguous non-technical regulatory language.

3. Whether HHS can process a provider's claims retroactively, once the provider's account is restored, notwithstanding 42 C.F.R. § 424.555.

LIST OF PARTIES

The parties in this case are: (1) Petitioner Willie H. Goffney, Jr., M.D., an individual; (2) Petitioner Advanced Surgical Associates Medical Office, Inc., a California corporation; and (3) Respondent Xavier Becerra, Secretary of the United States Department of Health and Human Services, in his official capacity.

The parties related to the administrative review performed by Respondent were: (a) Palmetto GBA, a contractor for the Centers for Medicare & Medicaid Services ("CMS"), which notified Petitioners of the deactivation; (b) Noridian Healthcare Solutions, LLC, a CMS contractor subsidiary of Noridian Mutual Insurance Company, which re-set Petitioners' billing date; (c) Administrative Law Judge Steven T. Kessel; and (d) Sheila Ann Hegy, Constance B. Tobias, and Leslie A. Sussan, members of the HHS Departmental Appeals Board. Plaintiffs-Appellants know of no intervenors or amici.

CORPORATE DISCLOSURE STATEMENT.

Willie H. Goffney, Jr., M.D. is an individual and Advanced Surgical Associates Medical Office, Inc. is a California corporation. There is no parent corporation or publicly-held corporation that owns ten percent (10%) or more of the stock of Advanced Surgical Associates Medical Office, Inc.

RELATED CASES.

- *Willie Goffney, Jr., M.D. v. Centers for Medicare & Medicaid Services,* HHS Departmental Appeals Board, Civil Remedies Division, Docket No. C-16-365, Decision No. CR4619. Decision entered May, 16, 2016.

- *In re Willie Goffney, Jr., M.D.,* HHS Departmental Appeals Board, Appellate Division, Docket No. A-16-121, Decision No. 2763. Final Decision on Review of Administrative Law Judge Decision entered Jan. 23, 2017.

- *In re Willie Goffney, Jr., M.D.,* HHS Departmental Appeals Board, Appellate Division, Docket No. A-17-67, Decision No. 2017-5. Ruling on Petition to Reopen Departmental Appeals Board Decision 2763 entered Sept. 15, 2017.

- *Willie H. Goffney, Jr. M.D., et al. v. Alex M. Azar, II, etc.,* U.S. District Court for the Central District of California, Western Division, Case No. 2:17-cv-08032-MRW. Judgment entered September 25, 2019.

- *Willie H. Goffney, Jr., M.D., et al. v. Xavier Becerra, etc.,* U.S. Court of Appeals for the Ninth Circuit, Case No. 19-563368. Judgment entered April 29, 2021.

- *Willie H. Goffney, Jr., M.D., et al. v. Xavier Becerra, etc.,* U.S. Court of Appeals for the Ninth Circuit, Case No. 19-563368. Rehearing Denied July 8, 2021.

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PETITION FOR A WRIT OF CERTIORARI

Willie H. Goffney, Jr., M.D. and Advanced Surgical Associates Medical Office, Inc. respectfully petition for a writ of certiorari of the United States Court of Appeals for the Ninth Circuit in this case.

INTRODUCTION

Judicial deference to administrative interpretation of regulations pursuant to *Auer v. Robbins*, 519 U.S. 452 (1997), continues to be unworkable and should be retired.

The court below, in a published opinion, demonstrated the inherent problem with courts continuing to apply the deference rule in *Auer*. The Ninth Circuit deferred to the administration's interpretation of regulatory wording even though the interpretation went directly against the unambiguous non-technical language of the regulations. If left intact, the opinion below not only continues a bias that the *Auer* deference rule imposes in favor of the federal government, but it also instructs other courts to defer to an administration's interpretation, even if the interpretation is plainly erroneous and concerns an unambiguous, non-technical regulation. For practical purposes, the ruling by the court below ends meaningful judicial review for Medicare providers, at least in the Ninth Circuit, despite the judicial review protections that Congress mandated in 5 U.S.C. § 706 and 42 U.S.C. § 405(g)

As Justice Gorsuch stated in *Kisor v. Wilkie*, --- U.S. ---, 139 S.Ct. 2400 (2019), the *Auer* deference rule, "with so many new and ambiguous limitations all but guarantees we will have to pass this way again." *Id.* at 2426. Petitioner respectfully submits that the time has come.

Further, in a case of first impression, the court below broadly interpreted 42 C.F.R. § 424.555 in a way the Secretary never had, holding that if the Department of Health and Human Services ("HHS") deactivates a provider's account—even erroneously—the provider can never recover any claims for services rendered prior to reinstatement. This interpretation effectively renders useless judicial review of an HHS deactivation decision.

OPINIONS BELOW.

- *Willie Goffney, Jr., M.D. v. Centers for Medicare & Medicaid Services,* HHS Departmental Appeals Board No. CR4619 (May 16, 2016).

- *In re Willie Goffney, Jr., M.D.,* HHS Department Appeals Board No. 2763 (Jan. 23, 2017).

- *In re Willie Goffney, Jr., M.D.,* HHS Departmental Appeals Board No. 2763 (Jan. 23, 2017).

- *Willie H. Goffney, Jr., M.D. v. Alex M. Azar, II, etc.,* U.S.D.C., C.D. Cal. Case No. 2:17-cv-08032-MRW (Dkt. 59), 2019 WL 13067036 (C.D. Cal. Sept. 25, 2019).

- *Goffney. v. Becerra,* 995 F.3d 737 (9th Cir. 2021).

JURISDICTION

The Ninth Circuit entered judgment on April 29, 2021.

The Ninth Circuit subsequently issued an order denying rehearing on July 8, 2021.

Title 28 U.S.C. § 1254(1) confers jurisdiction for Petitioners to have the case in the court of appeals reviewed by the Supreme Court pursuant to a writ of certiorari.

CONSTITUTIONAL AND STATUTORY PROVISIONS AND REGULATIONS INVOLVED.

The citations set forth below are set out verbatim in the Appendix.

42 U.S.C. § 405(g).
42 U.S.C. §§ 1395cc(h)(1)(A) and 1395cc(j)(8).
42 C.F.R. § 424.520.
42 C.F.R. § 424.540.
42 C.F.R. § 424.555.

STATEMENT OF THE CASE

A. Petitioner's Initial Application.

Petitioner is a surgical oncologist.[1] Since 1991, he has been practicing medicine in an underserved community in Long Beach, California. Excerpt of Record ("ER") 258, 672-73. In 1991, Petitioner enrolled as a provider in the Medicare program. ER 258, 459, 677. He has been in good standing ever since; his account has never been revoked, suspended, or terminated and he has never been disciplined. *Id.* For years, Medicare reimbursed Petitioners for medical services, including for surgeries removing tumors. ER 258-59.

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[1] Petitioner refers to Dr. Willie H. Goffney, Jr., a graduate of Harvard College and Harvard Medical School as well as a Fellow of the American College of Surgeons and a former member of the National Board of the American Cancer Society, Inc. ER 258; *see* Medical Board of California, https://search.dca.ca.gov, license number G52590.

B. CMS contractor Erroneously Deactivates Petitioner's Account; Petitioner Follows the CMS contractor's Instructions on How to Return to Active Status.

Yet, in 2008, Medicare stopped paying Petitioner's claims. Each time when Petitioner made inquiries, the contractor for the Centers for Medicare & Medicaid Services ("CMS") would say that it could not find his National Provider Identification ("NPI") number in the system. However, the NPI Enumerator would say his number ***was*** valid and, therefore, he could not apply for another one.[2] ER 260. Finally, four years later, on October 31, 2012, in response to Petitioner's multiple inquiries, the CMS contractor said that Petitioner's "PTAN [Provider Transaction Access Number] has been deactivated for non-billing since 2008." ER 460. The statement was false because Petitioner never stopped submitting claims. ER 258-59, 260. It also was a surprise; from 2008-12, the CMS contractor never sent a notice of possible or actual deactivation. ER 260, 755.

After receiving the October 2012 letter, Petitioner had extensive communications with the CMS contractor about rectifying the CMS contractor's

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[2] The problem likely occurred because Petitioner used his passport number ("PPN") to obtain his NPI. Physicians could obtain an NPI using their social security numbers ("SSNs") or PPNs. A minority of physicians used PPNs instead of SSNs. However, unbeknownst to providers, the computer system failed to treat NPIs equally. CMS contractors were able to view accounts with NPIs using SSNs, but not those using PPNs. Thus, certain physicians found their accounts erroneously deactivated, purportedly for nonsubmission of claims. ER 259-60.

errors. ER 260-61, 755-56. (Petitioner could not appeal the deactivation decision. 42 C.F.R. §§ 424.545(b) & 498.3(b).) Ultimately, in August 2015, the CMS contractor (Noridian Healthcare Solutions ("NHS")) told Petitioner that he needed to submit a revalidation certificate by selecting the revalidation box on Form 855. ER 721, 755-57. Replying to Petitioner's concerns that doing so might threaten his ability to have past claims processed, NHS allayed those concerns, saying that it would not affect his ability to have past claims processed. NHS stated, among other things, "[t]urning in [a revalidation] application should not disrupt your status. Revalidations are simply something that we use to make sure that the information that you have on file is correct." ER 721. In reliance on that statement, Petitioner submitted a revalidation certificate. ER 185-208, 752-53, 760.[3]

However, NHS breached its promise; it did exactly what Petitioner feared. It treated Petitioner's revalidation certificate as if it were an enrollment application and re-set his date for billing privileges. Accordingly, NHS would not accept any provider claims for services submitted prior to August 31, 2015. ER 456-58, 761-68.

Petitioner contends the CMS contractor denied Petitioner's claim based on a capricious and plainly erroneous regulatory interpretation, which an Administrative Law Judge ("ALJ") and the Health and Human Services Departmental Appeals Board

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[3] Petitioner's belief that his billing privileges would ***not*** be re-set by these events made perfect sense, given the language in the regulations, specifically 42 C.F.R. §§ 424.520, 424.540. (*See* Argument, Section I, *infra*.)

(the "Board") followed in lockstep. Accordingly, Petitioner sought relief through judicial review.

However, the court below, in a published opinion, deferred to the administration's interpretation of the regulatory wording despite the fact that the interpretation went against the unambiguous, non-technical language of the regulations. The decision below effectively eliminates meaningful judicial review under 5 U.S.C. § 706 and 42 U.S.C. § 405(g).

The court below also broadly interpreted 42 C.F.R. § 424.555, stating that a provider can never recover claims for services rendered prior to reinstatement. This interpretation effectively renders useless judicial review of an HHS deactivation decision.

Thus, despite being blameless for the administrative problems, Petitioner was denied payment for services he provided to Medicare patients, minimally from 2008 to 2015. ER 262.

C. Basis for Federal Jurisdiction.

Petitioners invoked jurisdiction in the district court under 28 U.S.C. §§ 1331 and 1346(a)(2) because the matter related to review of an administrative decision by HHS. The district court has jurisdiction to review final decisions of the HHS pursuant to 5 U.S.C. § 706 and 42 U.S.C. §§ 405(g), 1395cc(h)(1)(A), and 1395cc(j)(8). The district court entered a judgment on September 25, 2019 and Petitioners filed a timely notice of appeal to the Ninth Circuit. ER 30-43.

The Ninth Circuit had jurisdiction to consider an appeal of a district court's administrative review of

a decision by HHS under 42 U.S.C. § 405(g) and 28 U.S.C. § 1291.

This Court has jurisdiction under 28 U.S.C. § 1254(1) to review a decision by a court of appeals pursuant to a petition for a writ of certiorari.

REASONS FOR GRANTING THE WRIT

I. Regulatory Scheme: The Applicable Regulations – Section 520 and 540 – Are Straightforward And Concern Non-Technical Matters.

NHS, the ALJ, and the Board based their decision to re-set Petitioner's effective date for billing privileges on two regulations, 42 C.F.R. §§ 424.520 ("Section 520") and 424.540 ("Section 540").

Section 520(d) states that

> "The effective date for billing privileges for physicians . . . is the later of—
>
> "(1) The ***date of filing of a Medicare enrollment application*** that was subsequently approved by a Medicare contractor; or
>
> "(2) The date that the supplier first began furnishing services at a new practice location." (Emphasis added.)

Since Petitioner did not change locations, Section 520(d) mandates that the effective date for billing privileges is the date that Petitioner filed his enrollment application – 1991.

Section 540(b) provides that

> "(1) When deactivated for any reason ***other than nonsubmission of a claim,*** the provider or supplier must complete and submit a ***new enrollment application to reactivate its Medicare billing privileges*** or, when deemed appropriate, at a minimum, recertify that the enrollment information currently on file with Medicare is correct.
>
> "(2) ***Providers and suppliers deactivated for nonsubmission of a claim are required to recertify that the enrollment information currently on file with Medicare is correct*** and furnish any missing information as appropriate. The provider or supplier must meet all current Medicare requirements in place at the time of reactivation, and be prepared to submit a valid Medicare claim."[4] (Emphasis added.)

Reading these regulations together, it is apparent that once a provider submits its initial enrollment application, the date for setting billing privileges is established. Further, the date for billing privileges can only be re-set if a new enrollment application is submitted – a requirement if an account was deactivated due to any reason ***other than***

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[4] The quoted language is the version in effect up to November 4, 2019. The subsequent revision was simply to avoid repetition, to clarify, and to give CMS discretion to request additional information. Reg. 47,794, 47,839 (Sept. 10, 2019). The court below confined its "analysis to the version of the regulation that was in effect at the time of the events in this case." (Appendix at 10a.)

nonsubmission of a claim); the date is ***not*** re-set if an account was deactivated because of the nonsubmission of a claim, as no enrollment application is required in that instance.

Since Petitioner's account was deactivated for nonsubmission of a claim, he merely had to recertify that his information currently on file with Medicare is correct, which he did. His date for billing privileges should never have been re-set.

By creating a careful distinction between subsections 540(b)(1) and 540(b)(2) – *i.e.*, whether the account was deactivated for nonsubmission of a claim or for some other reason, the Secretary explicitly distinguished between when an enrollment application is required and when it is not. The significance of this distinction is made clear upon reading Section 520(d) – an enrollment application re-sets the date for billing privileges; a re-certification or revalidation application that the information is correct does not.

In fact, Section 540(b)(1) (which relates to deactivation for reasons *other than* nonsubmission of a claim) removes any doubt about its intent behind requiring a new enrollment application, stating that the purpose of the requirement to submit a new enrollment application of a claim is "to reactivate its Medicare billing privileges . . . ." The fact that the regulations distinguish between reactivating billing privileges if an account is deactivated for any reason other than nonsubmission of a claim, and ***not*** reactivating billing privileges if an account is deactivated only for nonsubmission of a claim, removes any argument that the language is ambiguous.

Thus, Sections 520(d) and 540(b) address non-technical matters and are unambiguous.

II. Congress Mandated Judicial Review of Agency Decisions.

Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq*., commonly known as the Medicare Act, establishes a federally subsidized health insurance program to be administered by the Secretary [of HHS]." *Heckler v. Ringer*, 466 U.S. 602, 605 (1984).

The Administrative Procedure Act of 1946, 5 U.S.C. § 706, provides that "the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and ***determine the meaning or applicability of the terms of an agency action***." *Id.* (emphasis added). Section 706 also provides that the reviewing court shall set aside agency conclusions found to be "arbitrary, capricious, and abuse of discretion or otherwise not in accordance of law; . . . without observance of procedure required by law, . . . unsupported by substantial evidence . . . or . . . unwarranted by the facts."

In addition, 42 U.S.C. § 405(g) provides that "[a]ny individual, after any final decision of the Commissioner of Social Security made after a hearing to which he was a party, irrespective of the amount in controversy, may obtain a review of such decision by a civil action . . . ." 42 U.S.C. §§ 1395cc(h)(1)(A) and 1395cc(j)(8) give a provider or supplier a right to obtain judicial review of decisions by the Department of Health and Human Services. *See, e.g., Stubbs v. Price,* 281 F.Supp.3d 1360, 1364 (N.D. Ga. 2017).

Accordingly, Congress afforded Petitioner and other providers and suppliers of Medicare services a right to judicial review concerning the decisions of the HHS, including administrative interpretations of regulations.

III. In The Case Below, The Court's Deference to the Board's Decision, Which Misinterpreted Straightforward Non-Technical Regulations, Showcases Why the *Auer* Rule Is Unworkable And Should Be Retired.

The *Auer* deference rule states that courts should defer to an administrative interpretation of a regulation under certain conditions. *Kisor,* 139 S.Ct. at 2424 (Chief Justice Roberts, concurring).

Justice Gorsuch explained in *Kisor* that "*Auer* requires judges to accept an executive agency's interpretation of its own regulations even when that interpretation doesn't represent the best and fairest reading." *Id.* at 2425 (Justice Gorsuch, concurring). Unfortunately, [t]his rule creates a 'systematic judicial bias in favor of the federal government, the most powerful of parties, and against everyone else.'" *Id.* (citing Larkin & Slattery, *The World After* Seminole Rock *and* Auer, 42 HARV. J. L. & PUB. POLICY 625, 641 (2019) (internal quotation marks omitted)). "This Court invented [the *Auer* deference rule], almost by accident and without any meaningful effort to reconcile it with the Administrative Procedure Act or the Constitution." 139 S.Ct. at 2425. Nevertheless, "*Auer* lives on," *id.,* continuing to wreak injustice to everyone other than the federal government.

Justice Kavanaugh echoed Justice Gorsuch's points about the unfair and unworkable *Auer* rule with a succinct analogy in his concurring opinion in *Kisor*: "Umpires in games at Wrigley Field do not defer to the Cubs manager's in-game interpretation of Wrigley's ground rules." *Id.* at 2448. It is improper for courts to defer to administrative interpretations of regulations when the court would reach a different conclusion.

Significantly, Chief Justice Roberts noted in his concurrence in *Kisor* that there is an important difference between deference to the administration and being persuaded by the administration's interpretation. Chief Justice Roberts stated that "there is a difference between holding that a court ought to be persuaded by an agency's interpretation and holding that it should defer to that interpretation under certain conditions." *Id.* at 2424. While Chief Justice Roberts suggested that the two would often overlap, the facts of the instant case show the unfairness that results as a practical matter when courts are instructed to defer to an agency's interpretation.

In her plurality opinion, Justice Kagan in *Kisor* tried to establish a refined deference rule that would be fair, cautioning courts that the

> "*Auer* deference is not the answer to every question of interpreting an agency's rules . . . . [T]he possibility of deference can arise only if a regulation is genuinely ambiguous. And when we use that term, we mean it—genuinely ambiguous, even after a court has resorted to all the standard tools of interpretation. Still more, not all

> reasonable agency constructions of those truly ambiguous rules are entitled to deference."

Id. at 2414. A court must carefully consider the text, structure, history, and purpose of a regulation before resorting to deference. *Id.* at 2415.

Unfortunately, the practical application of the *Auer* rule continues to be anything but fair. Perhaps nowhere are the results of this unjust rule more apparent than in the present case. The decision of the court below, while purportedly applying the *Auer* rule, actually created a rule that instructs other courts to defer to Board decisions, even if the Board is deciding a matter of first impression that goes directly against the plain, unambiguous non-technical language of the regulations.

A. By Deferring to a Board's Erroneous Interpretation of an Unambiguous Non-Technical Regulation, The Court Below Effectively Extinguishes A Provider's Right to Judicial Review Under 5 U.S.C. § 706 & 42 U.S.C. § 405(g).

In analyzing the deference question, the court below first considered whether the Board's decision was an official position of the Secretary. On this point, Justice Kagan in *Kisor* had stated that the official position "must be the agency's 'authoritative' or 'official position,' rather than any more ad hoc statement not reflecting the agency's views." *Id.* at 2416. "Not everything the agency does comes from, or is even in the name of, the Secretary or his chief advisers." *Id.* The regulatory "interpretation must at

the least . . . [be] understood to make authoritative policy in the relevant context." *Id.*

In the present case, the court below applied the *Auer* deference rule in a way that imposed judicial bias in favor of the federal government at every stage. It stated that a Board decision is *ipso facto* an official position of the Secretary interpreting a regulation. Appendix at 15a-17a. Prior to the opinion of the court below, other courts had to look to the *substance* of the Board's decision to determine if it was an authoritative policy in the relevant context. *See Kisor,* 139 S.Ct. at 2416. The Ninth Circuit's decision strips away this protection against agency abuse by declaring all Board decisions to be official positions.

Second and much more disturbing, the decision below addresses whether the matter involved the agency's substantive expertise or more naturally falls into a judge's bailiwick. Appendix at 15a-17a. Justice Kagan addressed this factor in *Kisor* by providing examples, stating that deference was not appropriate if the matter involved interpreting liability on parties for conduct not previously addressed. 139 S.Ct. at 2418. However, deference ***was*** warranted if the agency is deciding technical issues such as whether "a company created a new 'active moiety' by joining a previously approved moiety to lysine through a non-ester covalent bond." *Id.* at 2410, 2418. Although there might be reasons to follow administrative interpretations of technical regulations, no such rule should apply "when that interpretation doesn't represent the best and fairest reading." *Id.* at 2425 (Gorsuch, concurring).

Further, even though the present case involves interpreting liability for past claims on an issue not previously addressed, the court below stated that ***the***

Secretary has "comparative expertise" in resolving this question. By this statement, the court below has mandated that the job of interpreting plain regulatory language is now in the Secretary's bailiwick. Appendix at pp. 15a-17a. The problem with this pronouncement is that nearly every judicial review of a Secretary's decision involves examining regulatory language. Saying that the job of interpreting non-technical regulatory language is in the Secretary's bailiwick effectively denies providers judicial review under 5 U.S.C. § 706 and 42 U.S.C. § 405(g).

Third, the opinion below examined whether the regulatory interpretation is one that created unfair surprise or is consistent with other interpretations. Justice Kagan stated in *Kisor* that the Court had previously "refused to defer to an interpretation that would have imposed retroactive liability on parties for longstanding conduct that the agency had never before addressed." 139 S.Ct. at 2418 (citing *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 155-56 (2012)).

In the instant case, there was no precedent for the decision rendered by the Board. There was no basis in the law, in the Program Integrity Manual ("PIM"), or in any Board decisions for holding that a provider's account, which had been deactivated due to nonsubmission of a claim, should have a new effective date for billing privileges once the account is revalidated, thereby precluding payments for any past claims. Even the NHS assumed Petitioner's claims would be processed and paid after filing the revalidation certificate, stating, "You should have been able to keep your effective dates VS getting new ones." ER 734.

Further, Petitioner ***followed the explicit instructions of NHS as to how to correct the matter*** and receive payment for past claims. After Petitioner did that, NHS reversed course and denied all of his past claims. There can simply be no better example of an unfair surprise.[5]

Moreover, in reaching its conclusion, the court below relied on two HHS Board decisions; however, neither of those decisions apply. In *Urology Group of NJ, LLC*, 2018 WL 4144023 (HHS Departmental Appeals Board No. 2860, Mar. 23, 2018) ("*Urology Group*"), a group member died, but the group failed to self-report within 90 days as required. Medicare sent a request for an updated application; however, the doctors again failed to act. Six months later, Medicare followed up once more and deactivated the account. Twenty-three days after Medicare's second notice, the physicians submitted ***an enrollment application*** (not a revalidation certificate) and their account was reactivated, resulting in a 23-day gap. The gap made sense because the doctors repeatedly failed to act as required and because they submitted a new enrollment application. The Urology Group's reactivation after violating procedure and submitting a new enrollment application is not the same as a ***revalidation*** following nonsubmission of a claim in the instant case. Moreover, Section 540(b) makes the distinction explicitly clear – deactivations for reasons ***other than*** nonsubmission of a claim (like the deactivation in *Urology Group*) are treated differently

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[5] In fact, had Petitioner known about this possible interpretation, he could have greatly reduced his losses in 2012 by immediately filing a revalidation certificate rather than continuing to follow NHS's instructions from 2012-15.

than ones for nonsubmission of a claim (like the one in Petitioner's case).

Similarly, *In Re Arkady B. Stern, M.D.,* 2010 WL 3810867 (HHS Departmental Appeals Board No. 2329, Sept. 16, 2010), a physician was required to reactivate his billing privileges because of a change in location. *Id.* at *2. Dr. Stern had to submit a new application, checking the same box on Form 855 as if he had been deactivated for fraud or for losing his medical license. *See* ER 752-53. This is not the same as a revalidation following nonsubmission of a claim; the court below glossed over the crucial distinctions described in Section 540(b)(1) and Section 540(b)(2) between deactivations for reasons other than nonsubmission of a claim and deactivations for nonsubmission of a claim.

Neither of these cases suggest that a provider would think that a revalidation certificate (necessitated by a Medicare error in not acknowledging Petitioner's claims, resulting in a deactivation) would result in resetting billing privileges and a denial of years of valid claims for medical services.

Moreover, there should be no doubt that the decision was a surprise: The Board's decision was unprecedented, it went against any fair interpretation of Sections 520 and 540, it deprived Petitioner of years of payments for claims due to no fault of his own, and it even surprised the CMS contractor. To say that these compelling facts do not support an unfair surprise and, therefore, not enough to question deferring to the administrative decision, is to deny future providers an opportunity for judicial review based on allegations of unfair surprise.

Without question, the deference by the court below shows that judicial review under 5 U.S.C. § 706 or 42 U.S.C. § 405(g) is nothing more than a paper tiger. Even if a regulation relates to legal interpretations of non-technical regulatory wording about when claims can be processed, the court below mandates that courts must defer to the administrative decision. Even if the administrative interpretation involves a unprecedented issue that was a surprise to both the provider and the CMS contractor, the court below provides that courts should defer to the administrative decision. Even if common sense and the court's analysis would lead it to a different conclusion, the court below says that courts should defer to the administrative decision. Justice Gorsuch said that

> "Respectfully, we owe our colleagues on the lower courts more candid and useful guidance than this. And judges owe the people who come before them nothing less than a fair contest, where every party has an equal chance to persuade the court of its interpretation of the law's demands. . . . [¶] I would stop this business of making up excuses for judges to abdicate their job of interpreting the law, and simply allow the court of appeals to afford [litigants their] best independent judgment of the law's meaning."

Kisor, 139 S.Ct. at 2425-26 (Gorsuch, concurring).

In light of the way that the *Auer* deference rule is being applied, Petitioner respectfully requests that providers should have a fair contest. Courts should no

longer defer to administrative decisions when their own judgment would lead them to a different result. The *Auer* deference rule should be retired.

IV. The Broad Interpretation of 42 C.F.R. § 424.555[6] By The Court Below Prevents Providers From Obtaining Judicial Relief Under 5 U.S.C. § 706 and 42 U.S.C. § 405(g).

Section 555(b) states that

> "[n]o payment may be made for otherwise Medicare covered items or services . . . by a provider or supplier if the billing privileges of the provider or supplier are deactivated, denied, or revoked."

The decision below broadly interpreted Section 555 to hold that even if a CMS contractor erroneously deactivates a provider's account, the provider cannot obtain any relief once the account is restored to active status. Appendix at 11a-12a. To be clear, the court's interpretation of Section 555 was not based on deferring to an administrative decision; it was the court's own interpretation of this regulation. Nevertheless, the court's interpretation, combined with its deference to administrative interpretations of Sections 520 and 540, effectively removed any chance going forward that a provider might have to obtain meaningful judicial review.

The court below erred in its interpretation of Section 555 that a provider cannot be paid for claims when his/her account is inactive. Prior to the opinion

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[6] Referred to hereafter as "Section 555."

below, unpublished district court decisions had held that the CMS contractor could be responsible for processing older claims once the account is re-activated and in good standing. The Secretary did not invoke Section 555 to interfere with that just process. Even in the present case, neither the CMS contractor (NHS), the Administrative Law Judge (the "ALJ"), nor the HHS Board reviewing the ALJ's decision referenced Section 555 in any of their decisions. Similarly, the district court did not refer to Section 555 in its final order. None of them viewed Section 555 as an impediment to granting relief.

Moreover, in *Breton L. Morgan, M.D., Inc. v. Azar*, 2020 WL 1977123 (S.D. W.Va. Apr. 24, 2020) ("*Morgan*"), the court examined a request for legal fees that the Secretary owed to a physician. Dr. Morgan contended that the Secretary was liable for delays in not paying claims when an account was deactivated. While the district court in *Morgan* stated that Section 555 provided that claims should not be paid when an account is deactivated and therefore the Secretary did not improperly delay payment, it held that Section 555 has ***nothing to do*** with whether legitimate claims, which were made when an account was inactive, should not be paid once the account has become active again. 2020 WL 1977123, at *7.

The *Morgan* court's interpretation of Section 555 makes perfect sense. While Medicare should not pay providers when their accounts are not active, which is what Section 555 states, federal courts should not be denied flexibility to create a fair remedy for relief, when a provider's billing privileges are restored.

In reaching this decision on Section 555, the court below relied on *Urology Group*. However,

Urology Group is inapposite. The court below cited *Urology Group* for the Board's comment that a provider who has been deactivated for reasons ***other than nonsubmission of claims*** should not be entitled to reimbursement for services rendered during the period of deactivation. (Appendix at 12a (citing *Urology Group*).)[7]

Nevertheless, the court below uses Section 555 to prevent providers from ever obtaining relief once an account is restored, even if the government wrongfully deactivates an account. The court below effectively mandates that if an account is deactivated for nonsubmission of a claim – even erroneously – the provider can never recover for services provided during the time of the deactivation.

In the case at bar, a CMS contractor stalled for four years before telling Petitioner that his account had been deactivated due to nonsubmission of a claim. The CMS contractor then stonewalled for another three years before telling Petitioner he needed to file a revalidation certificate. Under the interpretation of Section 555 by the court below, however, even though the deactivation was an easily provable mistake, Petitioner had no right to recover payments for years

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[7] The *Urology Group* court's comment did not cite or reference Section 555 in support. Even so, the comment has nothing to do with a situation, such as in the present case, where a provider's account has been wrongly deactivated due to nonsubmission of a claim and is subsequently revalidated.

Although the court in *Urology Group* subsequently referenced Section 555 elsewhere in its decision, that later reference to Section 555 merely stated that Section 555 was designed to protect (a) from misuse of a billing number and/or (b) from overpayments. Yet, neither of those situations apply when an account is deactivated due to nonsubmission of a claim.

of claims providing Medicare patients with life-saving treatment.

Most importantly, if left intact, the opinion by the court below would end the right of physicians to obtain ***relief*** through judicial review. If the right to judicial review of Board decisions under 5 U.S.C. § 706 and/or 42 U.S.C. § 405(g) means anything, courts must have the ability to fashion relief to correct an injustice. As it is, the interpretation of Section 555 by the court below fatally dooms the chances that any provider would have to seek relief through judicial review of a Board decision.

CONCLUSION.

Petitioner explicitly followed every rule and every instruction from Medicare and its contractors. He did nothing wrong. When a computer error lost his account, he diligently contacted the CMS contractor and followed its instructions to rectify the problem in way that the CMS contractor said would allow Petitioner to recover for his unpaid Medicare claims. Yet, through no fault of his own, the administrative decisions and court rulings have denied him the chance to have his claims processed. He now faces the prospect that at least seven years of unpaid claims – claims for diligently removing cancerous tumors from Medicare patients in an underserved community – will not be paid.

Still, Petitioner's personal tragedy is not the reason why this Court should grant his petition for certiorari. It is because the decision of the court below effectively ends judicial review under 5 U.S.C. § 706 and 42 U.S.C. § 405(g). The court below demonstrated

that the *Auer/Kisor* rule on deference remains unworkable. It perpetuates "a systematic judicial bias in favor of the federal government, the most powerful of parties, and against everyone else." *Kisor*, 139 S.Ct. at 2425 (Gorsuch, concurring). Courts continue to defer to unique, *ad hoc* administrative interpretations that go directly against the plain non-technical language of regulations – in the instant case, Sections 520 and 540 – even if the interpretation was a surprise to the CMS contractor itself. The result is that courts are deprived of the proper guidance and litigants are deprived of a fair contest.

If deference in this instance is appropriate, then there may never be an opportunity for lower courts to do more than rubber-stamp administrative decisions. Providers and others contesting unfair administrative decisions will effectively be denied meaningful judicial review under 5 U.S.C. § 706 and 42 U.S.C. § 405(g).

In addition, the broad interpretation of Section 555 by the court should not stand. It guaranties that a provider will never be able to prevail in an effort to rectify a Secretary's unfair or erroneous deactivation decision.

Unless this petition for a writ of certiorari is granted and the opinion from the court below reversed, a provider will not be able to obtain meaningful relief – even if the provider is able to prove that a CMS contractor wrongfully deactivated his or her account.

The present case makes eminently clear that courts are continuing to apply the *Auer* deference rule in ways that impose great unfairness on litigants. The rule should be retired. Courts should be allowed to be

persuaded by an agency's interpretation, but not required to defer to that interpretation.

Petitioners therefore respectfully request that this Court grant this writ of certiorari in order to permit Medicare providers a right to meaningful judicial review under 5 U.S.C. § 706 and 42 U.S.C. § 405(g).

Respectfully submitted,

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APPENDICES

APPENDIX A

FOR PUBLICATION

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

WILLIE H. GOFFNEY, JR., M.D.; ADVANCED SURGICAL ASSOCIATES MEDICAL OFFICE, INC., a California corporation, *Plaintiffs-Appellants*, v. XAVIER BECERRA, Secretary of the United States Department of Health and Human Services, in his official capacity, *Defendant-Appellee.*	No. 19-56368 D.C. No. 2:17-cv-08032-MRW OPINION

Appeal from the United States District Court
for the Central District of California
Michael R. Wilner, Magistrate Judge, Presiding

Argued and Submitted March 2, 2021
Pasadena, California

Filed April 29, 2021

Before: Susan P. Graber, Stephen A. Higginson,* and Eric D. Miller, Circuit Judges.

Opinion by Judge Miller

SUMMARY**

Medicare

The panel affirmed the district court's summary judgment entered in favor of the Secretary of Health and Human Services ("HHS") in an action challenging HHS's denial of plaintiff Dr. Willie Goffney's claim for reimbursement from the Medicare program for services that he provided covered patients.

In 2012, Dr. Goffney was informed that his Medicare billing privileges had been deactivated in 2008. In 2015, Dr. Goffney attempted to reactivate his billing privileges. The Medicare contractor in his region, Nordian Healthcare Solutions, approved Dr. Goffney's request, but assigned him a new effective date of August 31, 2015 – the date on which he submitted the forms to reactivate his billing privileges. That effective date precluded Dr. Goffney from obtaining compensation for services he had performed in the preceding decade. The HHS Departmental Appeals Board affirmed the agency's denial of Dr. Goffney's petition for review, and

* The Honorable Stephen A. Higginson, United States Circuit Judge for the U.S. Court of Appeals for the Fifth Circuit, sitting by designation.

** This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

concluded that Dr. Goffney had filed a qualifying "enrollment application" and that the effective-date provision of 42 C.F.R. § 424.520(d) controlled.

The panel held that 42 C.F.R. § 424.520(d) was ambiguous, and did not specify whether a certification submitted to reactivate billing privileges constituted a "Medicare enrollment application" that triggered a new effective date. Specifically, the panel held that the parties' readings of other provisions of the regulations did not clearly resolve the ambiguity. The panel held that Section 424.555(b) supported the government's interpretation of "Medicare enrollment application" in this context. The panel further held that the regulatory history was not illuminating, and that considerations of purpose did not meaningfully affect its analysis.

The panel applied the principles of *Auer* deference to the agency's interpretation of its own regulations, and concluded that the interpretation reflected in the Departmental Appeals Board decision qualified for deference under *Auer*. Namely, section 424.520(d) was "genuinely ambiguous" in this context; the agency's reading fell within the permissible zone of ambiguity; and the agency's reading met all three of the additional criteria identified in *Kisor v. Wilkie*, 139 S. Ct. 2400 (2019). First, the Board's interpretation represented an authoritative statement of the agency. Second, the ambiguity implicated the agency's core expertise because it involved the administration of the Medicare program. Third, the agency's reading was consistent with how it had previously interpreted the relevant regulations. The panel concluded that under the agency's interpretation of section 424.520(d), Dr. Goffney's reactivation request was "a Medicare enrollment application" and its filing date of

August 31, 2015 was the effective billing date of his billing privileges.

The panel held that the district court did not abuse its discretion in denying Dr. Goffney's motion to order HHS to supplement the administrative record.

COUNSEL

Charles G. Smith (argued) and Dana M. Silva, Law Offices of Charles G. Smith, Sherman Oaks, California, for Plaintiffs-Appellants.

Daniel Aguilar (argued) and Mark B. Stern, Appellate Staff; Nicola T. Hanna, United States Attorney; Civil Division, United States Department of Justice, Washington, D.C.; for Defendant-Appellee.

OPINION

MILLER, Circuit Judge:

Dr. Willie Goffney sought reimbursement from the Medicare program for services that he provided to covered patients. Applying its interpretation of the governing regulation, the Department of Health and Human Services (HHS) denied his claim. The Supreme Court recently reaffirmed that a reviewing court should defer to an agency's reasonable interpretation of ambiguous regulations. *Kisor v. Wilkie*, 139 S. Ct. 2400 (2019). We agree with the district court that the governing regulation is genuinely ambiguous and that the agency's interpretation is reasonable. We also agree with the district court that its review was appropriately

confined to the administrative record the agency produced and that the agency was not required to supplement the record. We therefore affirm.

I

Medicare is a federally subsidized medical insurance program for the elderly and disabled. *See* 42 U.S.C. § 1395 *et seq.*; *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 506 (1994). The Centers for Medicare & Medicaid Services (CMS), an agency within HHS, oversees the Medicare program. *See Pharmaceutical Rsch. & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 650 n.3 (2003). CMS contracts with private entities to administer the program. *See* 42 U.S.C. §§ 1395u(a), 1395kk-1(a); 42 C.F.R. § 421.5(b). Each Medicare contractor is responsible for a particular region of the country. 42 C.F.R. § 421.404(b)(1), (c)(1).

To be paid for performing Medicare services, healthcare providers must enroll in the program, at which point they receive billing privileges and a billing number. 42 C.F.R. § 424.505. (The statute distinguishes between hospitals, which it calls "providers," and physicians, whom it calls "suppliers," but because nothing in this case turns on that distinction, we will refer to both as providers. 42 U.S.C. § 1395x(d), (u).) Billing privileges are not permanent—once approved, they may be revoked or deactivated. 42 C.F.R. § 424.555(b). A revocation "means that . . . billing privileges are terminated." *Id.* § 424.502. A deactivation "means that . . . billing privileges were stopped, but can be restored upon the submission of updated information." *Id.* Deactivation exists "to protect the provider . . . from misuse of its billing number and to protect the Medicare Trust Funds from unnecessary overpayments." *Id.* § 424.540(c).

Goffney is a surgical oncologist in Long Beach, California, who has provided services to Medicare patients since 1991. In 2005, Goffney stopped receiving payments for his Medicare claims, but he nonetheless continued to provide services to Medicare patients for the next decade. It is not clear—at least to us—exactly what happened during that period. The record suggests that Goffney provided services, received no payments, and made only occasional efforts to remedy the situation. But the exact sequence of events is not relevant to the legal issue before us.

In 2012, Goffney was informed that his Medicare billing privileges had been deactivated in 2008 because he had not submitted a claim for more than a year. *See* 42 C.F.R. § 424.540(a)(1). Goffney argues that the deactivation was erroneous, but although the regulations provide a mechanism for a provider to challenge a deactivation, Goffney did not invoke that mechanism. *See* 42 C.F.R. §§ 405.374(a), 405.375(a), 424.545(b).

Instead, in 2015, Goffney attempted to reactivate his billing privileges. To do so, he submitted documents to Noridian Healthcare Solutions, the Medicare contractor in his region, verifying that his enrollment information had not changed. Specifically, he submitted portions of Forms CMS-855B, CMS-855I, and CMS-855R—entitled "Medicare Enrollment Application"—which providers use for initial enrollment in the program, reactivation, and various other purposes. Goffney checked the box stating that he was "revalidating [his] Medicare enrollment."

Goffney hoped—and, he says, a Noridian employee represented—that by recertifying the accuracy of his information, he could keep his original effective billing date and be paid for the services he had provided while his privileges were inactive. But when Noridian approved

Goffney's request, it assigned him a new effective date of August 31, 2015—the date on which he had submitted the forms to reactivate his billing privileges. That effective date precluded Goffney from obtaining compensation for services he had performed in the preceding decade.

Goffney sought reconsideration, but Noridian denied his request. It relied on 42 C.F.R. § 424.520(d), which provides that "[t]he effective date for billing privileges for physicians" is "[t]he date of filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor." Reasoning that what Goffney filed on August 31, 2015 was an "enrollment application," Noridian concluded that section 424.520(d) made that date the effective date of his reactivated billing privileges.

Goffney then petitioned for review before an HHS administrative law judge, arguing that a certification attesting to the accuracy of existing enrollment information does not constitute an "enrollment application" under section 424.520(d). The administrative law judge denied Goffney's petition.

The HHS Departmental Appeals Board affirmed. The Board concluded that Goffney had filed a qualifying "enrollment application" and that the effective-date provision of section 424.520(d) controlled. The Board emphasized that no other regulation sets the effective date for Medicare billing privileges. The Board also determined that it lacked authority to consider the circumstances surrounding Goffney's initial deactivation, the Medicare claims he submitted while his billing privileges were inactive, or his equitable arguments about Noridian's representations to him.

Having exhausted his administrative remedies, Goffney sought review of the agency's decision in federal district court. *See* 42 U.S.C. §§ 405(g), 1395cc(h)(1)(A). Goffney asked the district court to order the agency to supplement the administrative record to include additional materials related to the agency's decision. The district court denied the motion.

The district court granted summary judgment to the Secretary of HHS. The court reasoned that HHS regulations contain "a pretty obvious silence . . . about whether a *past* 'effective date' is warranted following reactivation," and therefore the "regulations are 'genuinely ambiguous' in this area." It concluded that the agency's interpretation of the regulations was entitled to deference and that the agency had "provided a reasonable basis for applying the Section 424.520 effective date to [Goffney's] circumstance."

II

In this appeal, Goffney does not challenge the agency's conclusions about the scope of its authority, nor does he dispute that the agency correctly identified August 31, 2015 as the date on which he submitted his reactivation request. He also does not dispute that under section 424.520(d), "[t]he effective date for billing privileges for physicians [is] the date of filing of a Medicare enrollment application that was subsequently approved." The sole question before us is whether Goffney's reactivation request constituted a "Medicare enrollment application" within the meaning of section 424.520(d), such that its filing date of August 31, 2015 is the effective date of his billing privileges. More specifically, the question before us is whether to accept the Departmental Appeals Board's interpretation of section 424.520(d)'s phrase "Medicare enrollment application."

The Supreme Court has held that an agency's interpretation of its own regulation is entitled to deference when, among other things, the regulation is "genuinely ambiguous." *Kisor*, 139 S. Ct. at 2415. With that in mind, we first "exhaust all the 'traditional tools' of construction" in an effort to interpret the regulation by examining its "text, structure, history, and purpose." *Id.* (quoting *Chevron U.S.A. Inc. v. NRDC, Inc.*, 467 U.S. 837, 843 n.9 (1984)); *see Minnick v. Commissioner*, 796 F.3d 1156, 1159 (9th Cir. 2015) (per curiam) ("Regulations are interpreted according to the same rules as statutes, applying traditional rules of construction."). Because we conclude that the regulation is ambiguous, we then consider what principles of deference apply.

A

Section 424.520(d) itself does not specify whether a certification submitted to reactivate billing privileges constitutes a "Medicare enrollment application" that triggers a new effective date. The parties direct us to various other provisions of the regulations. One supports Goffney's reading and others support the government's, and they do not clearly resolve the ambiguity.

The regulations contain a definitional section, and because an express textual definition would be controlling, we begin there. *See Burgess v. United States*, 553 U.S. 124, 129–30 (2008). Unfortunately, "Enrollment application" is defined unhelpfully, for our purposes, as "a CMS-approved paper enrollment application or an electronic Medicare enrollment process." 42 C.F.R. § 424.502. "Enroll/Enrollment" are also defined terms, but their definitions shed no more light. *Id.* They refer to "the process that Medicare uses to establish eligibility to submit claims for Medicare-covered items and services," which includes

"validating the provider['s] eligibility to provide items or services to Medicare beneficiaries" and "granting the Medicare provider . . . Medicare billing privileges." *Id.* The reference to "granting . . . billing privileges" could perhaps be construed to encompass the reactivation of billing privileges, but even on that understanding, it would not necessarily follow that a request for reactivation would constitute a "Medicare enrollment application" under section 424.520(d).

Goffney principally relies on 42 C.F.R. § 424.540(b) (2012), entitled "Deactivation of Medicare billing privileges." Although that provision has since been amended, the amendment is not relevant to the issue in this case, and the agency's commentary explains that it was intended simply to reduce "confusion" by "clarif[ying]" the language of the rule. Medicare, Medicaid, and Children's Health Insurance Programs; Program Integrity Enhancements to the Provider Enrollment Process, 84 Fed. Reg. 47,794, 47,839 (Sept. 10, 2019). We therefore confine our analysis to the version of the regulation that was in effect at the time of the events in this case.

Section 424.540(b) outlines two procedures by which a provider can reactivate billing privileges. A provider who has been "deactivated for any reason other than nonsubmission of a claim . . . must complete and submit a new enrollment application to reactivate its Medicare billing privileges or, when deemed appropriate, at a minimum, recertify that the enrollment information currently on file with Medicare is correct." 42 C.F.R. § 424.540(b)(1) (2012). On the other hand, a provider deactivated for nonsubmission of a claim need only "recertify that the enrollment information currently on file with Medicare is correct and

furnish any missing information as appropriate." *Id.* § 424.540(b)(2) (2012).

Goffney emphasizes that only paragraph (b)(1) refers to the filing of a "new enrollment application." In his view, section 424.540(b) creates a negative implication that when a provider is deactivated for "nonsubmission of a claim"—as Goffney was—the provider need not submit a "new enrollment application." But while that is a reasonable inference, it is not conclusive here. Section 424.520(d) provides for an effective billing date upon the contractor's receipt of an "enrollment application"—unlike section 424.540(b), it does not contain the qualifier "new." So while there is a strong argument that what Goffney filed was not a "*new* enrollment application," his filing might still have been an "enrollment application."

The government points to two other provisions, and while they both support its alternative reading, neither is decisive. First, 42 C.F.R. § 424.515 states that Medicare providers "must resubmit and recertify the accuracy of [their] enrollment information every 5 years," a process that involves submitting an "enrollment application and supporting documentation," *id.* § 424.515(a). That provision suggests that the term "enrollment application" can describe more than just a provider's very first submission to enroll in Medicare—and that a recertification, at least in this context, might be one example of what is included. *Accord id.* §§ 405.818, 424.510(d)(3)(ii) (both using the term "enrollment application" in other contexts that appear not to be restricted to initial enrollment).

Second, the government relies on 42 C.F.R. § 424.555(b), which restricts the government's payment liability by specifying that "[n]o payment may be made for otherwise Medicare covered items or services furnished to a

Medicare beneficiary by a provider . . . if the billing privileges of the provider . . . are deactivated, denied, or revoked." The government reads that provision to mean that a provider cannot ever bill Medicare for services that it renders while its billing privileges are deactivated. If that is true, it logically follows that the effective date of a provider's billing privileges should be reset upon the reactivation of those privileges. *See* 42 C.F.R. § 424.5(a)(2). Goffney responds that section 424.555(b) just means that a provider must have reactivated its billing privileges by the time of payment.

We think the government has the better reading of section 424.555(b) because another regulation provides that the agency will make payments only if "[t]he services [were] furnished by a provider . . . that was, at the time it furnished the services, qualified to have payment made for them." 42 C.F.R. § 424.5(a)(2). That interpretation also accords with section 424.555(c), which states that providers that furnish services for which section 424.555(b) prohibits payment are responsible for "any expense incurred" in providing those services. If a provider could seek retrospective payments once it reestablished its billing privileges, section 424.555(c) would make little sense. Although the regulations do permit retrospective billing in certain narrow circumstances, *see*, *e.g.*, 42 C.F.R. § 424.521(a), HHS has not allowed that practice as a general matter, *see Urology Grp. of NJ, LLC*, DAB No. 2860, 2018 WL 4144023 (H.H.S. 2018) (explaining that "a deactivated provider . . . was not intended to be entitled to Medicare reimbursement for services rendered during the period of deactivation"). Section 424.555 thus supports the government's interpretation of "Medicare enrollment application" in this context.

Finally, we consider the regulatory history and purpose. *See Kisor*, 139 S. Ct. at 2415. The history is not illuminating, and we conclude that considerations of purpose do not meaningfully affect our analysis. Section 424.540(c) states that the agency deactivates billing privileges "to protect the provider . . . from misuse of its billing number and to protect the Medicare Trust Funds from unnecessary overpayments." The government argues that this purpose would be frustrated if the agency had to presume that every claim submitted during a period of deactivation was legitimate, and that to avoid that result, it must set a new effective billing date. That justification makes some sense, especially in a case like this one, in which the provider's billing privileges were apparently inactive for a decade. (To be clear, the record contains no suggestion that any of Goffney's claims were fraudulent.)

On the other hand, regulations, like statutes, often reflect compromises among competing objectives, and "it is quite mistaken to assume . . . that 'whatever' might appear to 'further[] the statute's primary objective must be the law.'" *Henson v. Santander Consumer USA Inc.*, 137 S. Ct. 1718, 1725 (2017) (alteration in original) (quoting *Rodriguez v. United States*, 480 U.S. 522, 526 (1987) (per curiam)). And even under Goffney's reading of section 424.555(b), the agency would not be required to pay claims submitted during a period of deactivation until after the provider's billing privileges were reactivated. In that situation, the provider would have confirmed the accuracy of its information, so there would be little reason to suspect that past claims were fraudulent. The regulations also set time limits on when claims can be filed—generally within one year of the service, *see* 42 C.F.R. § 424.44—further reducing the concern about fraudulent billing. The regulatory purpose therefore does not help us resolve the textual ambiguity.

B

Because this case "involves an interpretation of an administrative regulation," we must "look to the administrative construction of the regulation if the meaning of the words used is in doubt." *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 413–14 (1945). When an agency interprets its own ambiguous regulation, the agency's interpretation is generally "of controlling weight unless it is plainly erroneous or inconsistent with the regulation." *Id.* at 414. Although *Seminole Rock* represents one of the Supreme Court's earliest expositions of that principle, the doctrine has come to be associated with the Court's more recent decision in *Auer v. Robbins*, 519 U.S. 452, 461 (1997).

The Supreme Court recently reaffirmed *Auer* deference, but in doing so, it noted some limitations on the doctrine's scope. *See Kisor*, 139 S. Ct. at 2408. The most important limitation is that the regulation must be "genuinely ambiguous." *Id.* at 2415; *Christensen v. Harris County*, 529 U.S. 576, 588 (2000). In other words, a court may not "wave the ambiguity flag" and abandon its interpretive efforts simply because the regulation appears "impenetrable on first read" or "make[s] the eyes glaze over." *Kisor*, 139 S. Ct. at 2415. Instead, a court must first "exhaust all the 'traditional tools' of construction" and consider the regulation's "text, structure, history, and purpose," just as it would "if it had no agency to fall back on." *Id.* (quoting *Chevron*, 467 U.S. at 843 n.9). Even then, it may defer only to an agency interpretation that is "reasonable," *Thomas Jefferson Univ.*, 512 U.S. at 515, in the sense that it falls within the permissible "zone of ambiguity" created by the regulation. *Kisor*, 139 S. Ct. at 2415–16.

Although *Auer* deference to an agency's interpretation of a regulation is conceptually distinct from *Chevron* deference

to an agency's interpretation of a statute, the two forms of deference operate in similar ways. *See Kisor*, 139 S. Ct. at 2416 (rejecting the suggestion that "agency constructions of rules receive greater deference than agency constructions of statutes"). Like *Auer* deference, *Chevron* deference applies only if a court first deems a statute ambiguous after exhausting "traditional tools of statutory construction." *Chevron*, 467 U.S. at 843 n.9; *Turtle Island Restoration Network v. United States Dep't of Com.*, 878 F.3d 725, 733 (9th Cir. 2017). And even when a statute is ambiguous at *Chevron* step one, the agency's resolution of the ambiguity must be reasonable to survive step two. *Compare Chevron*, 467 U.S. at 845, *with Kisor*, 139 S. Ct. at 2415–16. In other words, "where Congress has established an ambiguous line, the agency can go no further than the ambiguity will fairly allow." *City of Arlington v. FCC*, 569 U.S. 290, 307 (2013); *see United States v. Home Concrete & Supply, LLC*, 566 U.S. 478, 493 n.1 (2012) (Scalia, J., concurring in part and concurring in the judgment) ("It does not matter whether the word 'yellow' is ambiguous when the agency has interpreted it to mean 'purple.'"); *Global Tel*Link v. FCC*, 866 F.3d 397, 419 (D.C. Cir. 2017) (Silberman, J., concurring).

The Court in *Kisor* held that even if those threshold requirements are satisfied, an agency's interpretation must satisfy three other criteria to merit deference under *Auer*. *See Kisor*, 139 S. Ct. at 2416–18. First, the interpretation "must be the agency's 'authoritative' or 'official position,'" and not merely an "ad hoc statement not reflecting the agency's views." *Id.* at 2416 (quoting *United States v. Mead Corp.*, 533 U.S. 218, 257–59, 258 n.6 (2001) (Scalia, J., dissenting)). That means that the interpretation must "emanate from those actors, using those vehicles,

understood to make authoritative policy in the relevant context." *Id.*

Second, "the agency's interpretation must in some way implicate its substantive expertise." *Kisor*, 139 S. Ct. at 2417; *see Martin v. Occupational Safety & Health Rev. Comm'n*, 499 U.S. 144, 152–53 (1991). The "most obvious" situation in which that criterion is satisfied is "when a rule is technical." *Kisor*, 139 S. Ct. at 2417. But it can also be satisfied in situations involving "more prosaic-seeming questions" as long as the agency has some "comparative expertise" and the issue is not one that "fall[s] more naturally into a judge's bailiwick." *Id.*; *see City of Arlington*, 569 U.S. at 309 (Breyer, J., concurring in part); *cf. Adams Fruit Co. v. Barrett*, 494 U.S. 638, 649–50 (1990).

Third, the interpretation must reflect the agency's "fair and considered judgment." *Kisor*, 139 S. Ct. at 2417 (quoting *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 155 (2012)). That does not mean that the agency must engage in an exhaustive interpretive discussion—even an interpretation implicit in an agency's order can reflect the agency's "fair and considered judgment." *See Association of Bituminous Contractors, Inc. v. Apfel*, 156 F.3d 1246, 1252 (D.C. Cir. 1998); *accord Southern Utah Wilderness All. v. Office of Surface Mining Reclamation & Enf't*, 620 F.3d 1227, 1236 (10th Cir. 2010). Rather, this part of the test protects reliance interests associated with longstanding agency practices or interpretations. Courts may not defer to an interpretation that "creates 'unfair surprise' to regulated parties" or that amounts "to a merely 'convenient litigating position.'" *Kisor*, 139 S. Ct. at 2417–18 (first quoting *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 170 (2007), and then quoting *Christopher*, 567 U.S. at 155).

C

Applying those principles here, we conclude that the interpretation reflected in the Departmental Appeals Board's decision qualifies for deference under *Auer*. As we have explained, section 424.520(d) is "genuinely ambiguous" in this context, and the agency's reading falls within the permissible zone of ambiguity. *Kisor*, 139 S. Ct. at 2415–16. And the agency's reading meets all three of the additional criteria identified in *Kisor*.

First, the Board's interpretation represents an authoritative statement of the agency. The Secretary of HHS appoints the Board's members, 45 C.F.R. § 16.5(a), and the Board "generally issues HHS's final decision, which may then be appealed to a federal court." *Arizona Health Care Cost Containment Sys. v. McClellan*, 508 F.3d 1243, 1248 n.6 (9th Cir. 2007). The Board's decision is the product of a formal process that merits deference. *Cf. id.* at 1249, 1253–54 (deferring under *Chevron* to the Board's interpretation of an ambiguous statute).

Second, the ambiguity implicates the agency's core expertise because it involves the administration of the Medicare program. *See Kisor*, 139 S. Ct. at 2417. The regulatory scheme allows providers to bill only in certain circumstances and limits their ability to receive Medicare payments depending on their billing status. *See* 42 C.F.R. §§ 424.521(a), 424.555(b). The regulations also reflect HHS's policy of deactivating billing privileges to prevent Medicare fraud and to protect the public fisc. *See* 42 C.F.R. § 424.540(c). The ambiguity here affects the implementation of that policy, and the agency has "comparative expertise" in resolving the issue. *Kisor*, 139 S. Ct. at 2417. *See generally Urology Grp. of NJ*, DAB No. 2860.

Third, far from being a new interpretation or one that would create unfair surprise, the agency's reading is consistent with how it has previously interpreted the relevant regulations. *See Kisor*, 139 S. Ct. at 2417–18; *cf. Christopher*, 567 U.S. at 155–57. CMS's Program Integrity Manual (PIM)—a guidebook that instructs Medicare contractors on how to process provider applications, pay claims, and minimize fraud—has long required contractors to reset providers' effective billing dates when they grant reactivation requests. *See Urology Grp. of NJ*, DAB No. 2860 (explaining that since 2009, the PIM has treated a "reactivation application . . . as an initial enrollment application" for purposes of section 424.520(d) (quoting Medicare Program Integrity Manual § 10.6.1.4 (rev. 289, Jan. 1, 2009))); *see also* Medicare Program Integrity Manual § 15.27.1.2 (rev. 865, Mar. 12, 2019); *id.* § 15.27.1.2.1 (rev. 765, Jan. 1, 2018); *id.* § 15.27.1.2.2 (rev. 765, Jan. 1, 2018). More than a decade ago, the Board recognized, if not tacitly endorsed, that interpretation. *See Arkady B. Stern*, DAB No. 2329, 2010 WL 3810867, at *3 & n.5 (H.H.S. 2010) (interpreting the PIM to mean that "a reactivated provider will have a new effective date"). Indeed, when Noridian denied Goffney's reconsideration request, it cited the PIM for the same principle.

As currently written, section 15.27.1.2.2(A) of the PIM requires providers seeking reactivation to submit a packet of documents that CMS calls a "reactivation certification package," even if their enrollment information has not changed. Section 15.27.1.2 says that if "the contractor approves a provider's . . . reactivation application or reactivation certification package . . . the reactivation effective date shall be based on the date the contractor received the application or [reactivation certification package]." The PIM therefore directly resolves the

ambiguity at issue here. And even though the PIM, like its counterpart in the social security context, "does not impose judicially enforceable duties," *Lockwood v. Commissioner Soc. Sec. Admin.*, 616 F.3d 1068, 1073 (9th Cir. 2010); *see* 42 C.F.R. § 405.1062(a), it still shows that HHS's interpretation is more than just a "convenient litigating position," *Christopher*, 567 U.S. at 155.

Goffney argues that the Board's decision was not a "fair and considered judgment" because it was "*ad hoc*"; it "ignore[d] the plain language of Section 520"; and it did not cite "any legal precedent or administrative rules." We disagree. The Board invoked section 424.520(d), quoted the relevant "recertification" language from section 424.540(b), and recognized that the contractor had "treated [Goffney's request] as an application . . . to reactivate his billing privileges." Even if its analysis could have been more comprehensive, the Board resolved the legal question of whether section 424.520(d) applies to reactivation requests like Goffney's. *See Association of Bituminous Contractors*, 156 F.3d at 1252.

We conclude that the Board's interpretation of section 424.520(d) merits *Auer* deference and controls this case. *See* 519 U.S. at 461. Under that interpretation, Goffney's reactivation request was "a Medicare enrollment application," and its filing date of August 31, 2015 is the effective date of his billing privileges.

III

The district court did not abuse its discretion in denying Goffney's motion to order HHS to supplement the administrative record. *See Lands Council v. Powell*, 395 F.3d 1019, 1030 n.11 (9th Cir. 2005). Goffney argues that the agency failed to include in the record all materials

related to its decision to assign him an August 31, 2015 effective billing date. In his view, "[t]he missing documents likely show that the Agency's decision was arbitrary and capricious." He does not, however, identify any specific documents that he believes to be missing.

The Administrative Procedure Act requires us to review an agency's action based on "the whole record." 5 U.S.C. § 706. That "includes everything that was before the agency pertaining to the merits of its decision." *Portland Audubon Soc'y v. Endangered Species Comm.*, 984 F.2d 1534, 1548 (9th Cir. 1993); *see Thompson v. United States Dep't of Labor*, 885 F.2d 551, 555–56 (9th Cir. 1989) ("The 'whole' administrative record . . . consists of all documents and materials directly or indirectly considered by agency decision-makers." (emphasis omitted) (quoting *Exxon Corp. v. Department of Energy*, 91 F.R.D. 26, 33 (N.D. Tex. 1981))). HHS has codified that requirement in a regulation that directs the Office of Medicare Hearings and Appeals—the agency tasked with compiling the record for HHS administrative proceedings—to include in the record "the appealed determinations, and documents and other evidence used in making the appealed determinations and the ALJ's or attorney adjudicator's decision," as well as any proffered evidence excluded by the adjudicator. 42 C.F.R. § 405.1042(a)(2).

We have explained that a court reviewing an agency's action may examine "extra-record evidence" only in "limited circumstances" that are "narrowly construed and applied." *Lands Council*, 395 F.3d at 1030 (citing *Camp v. Pitts*, 411 U.S. 138, 142–43 (1973) (per curiam)). Such circumstances are present, for example, when "the agency has relied on documents not in the record" or "when plaintiffs make a showing of agency bad faith." *Id.* (quoting

Southwest Ctr. for Biological Diversity v. United States Forest Serv., 100 F.3d 1443, 1450 (9th Cir. 1996)); *see Department of Com. v. New York*, 139 S. Ct. 2551, 2573–74 (2019); *Portland Audubon Soc'y*, 984 F.2d at 1548. But like other official agency actions, an agency's statement of what is in the record is subject to a presumption of regularity. *See Angov v. Lynch*, 788 F.3d 893, 905 (9th Cir. 2015). We must therefore presume that an "agency properly designated the Administrative Record absent clear evidence to the contrary." *Bar MK Ranches v. Yuetter*, 994 F.2d 735, 740 (10th Cir. 1993); *accord Oceana, Inc. v. Ross*, 920 F.3d 855, 865 (D.C. Cir. 2019); *see also Angov*, 788 F.3d at 905 ("[I]n the absence of clear evidence to the contrary, courts presume that [government officials] have properly discharged their official duties." (quoting *National Archives & Records Admin. v. Favish*, 541 U.S. 157, 174 (2004))).

Goffney has not presented "clear evidence"—or any evidence at all. His argument rests on speculation that the agency must have considered more documents than it said it had because, in his view, the agency's decision was "unprecedented." As the district court recognized, however, Goffney's petition posed a legal issue, not a factual one. Noridian's denial of Goffney's reconsideration request shows that Noridian reviewed Goffney's application, section 424.520(d), the PIM, and Noridian's policy about its authority to set billing privileges. It does not follow that there must be additional documents underpinning Noridian's decision. Nor is there any indication that the ALJ or the Board relied on any other materials in reaching their decisions.

Goffney also claims that CMS's decision "to deny benefits in this manner appeared only to apply to physicians of color" and that the agency has "manipulate[d] the

administrative record" to shield it from review. In his district court filings, Goffney did not so much as hint at the possibility of racial bias; to the contrary, he stated that "there is no allegation of bad faith in this case." Goffney has provided no evidence of bias, and the record reveals none.

AFFIRMED.

APPENDIX B

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

No. 19-56368
D.C. No. 2:17-cv-08032 MRW

WILLIE H. GOFFNEY, Jr. M.D., ET AL.,
Plaintiffs-Appellants,

v.

XAVIER BECCERA [*sic*]**, etc.**
Defendant-Appellee.

ORDER

Before Graber, Higginson,* and Miller, Circuit Judges.

The panel has unanimously voted to deny appellants' petition for rehearing. Judge Graber and Judge Miller have voted to deny the petition for

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* The Honorable Stephen A. Higgenson, United States Circuit Judge for the U.S. Court of Appeals for the Fifth Circuit, sitting by designation.

rehearing en banc, and Judge Higginson so recommends. The full court has been advised of the petition for rehearing en banc, and no judge has requested a vote on whether to rehear the matter en banc. Fed. R. App. P. 35.

The petitions for rehearing and rehearing en banc are DENIED.

APPENDIX C

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

No. 2:27-cv-08032-MRW
2019 WL 13067036

WILLIE H. GOFFNEY, JR., M.D., ET AL.,

Plaintiffs,

v.

ALEX M. AZAR, II, ETC.,

Defendant.

CIVIL MINUTES – GENERAL

Before Hon. Michael R. Wilner, U.S. Magistrate Judge,

ORDER AFFIRMING AGENCY DECISION

Proceedings:

***1** 1. The Court heard from the parties at a hearing regarding the tentative decision. After considering the arguments of the lawyers and re-reviewing the Kisor opinion, the Court adopts its tentative decision as its final ruling in the case.

2. The only modification: the Court will note that its first citation to Kisor likely represented the opinion of the plurality (not that of the Supreme Court) when summarizing the historic background of Auer deference. But the later citation to Kisor at pages 2417-18 regarding the substance of the regulatory analysis clearly included Chief Justice Roberts – he joined in the opinion and "agree[d] with the Court's treatment in Part II-B of the bounds of Auer deference." Kisor, 139 S. Ct. at 2424 (Roberts, C.J., concurring).

3. The Court expressly declines to address Plaintiffs' argument that the ALJ allegedly applied the incorrect standard of review to the contractor's adverse decision. Plaintiffs asserted this argument in their reply submission, not the opening brief on appeal from the agency. (Docket # 51 at 9.) The general rule is that parties "cannot raise a new issue for the first time in their reply briefs." Eberle v. City of Anaheim, 901 F.2d 814, 818 (9th Cir. 1990) (quotation omitted); Globefill Inc. v. Elements Spirits, Inc., 756 F. App'x 764, 766 (9th Cir. 2019) (same). To the extent that Plaintiffs merely sought to refute a statement in the government's brief, that is also insufficient to preserve

(or, as Plaintiffs attempted to do at the hearing, advance) the argument in this district court.

4. The remainder of the presentation articulately re-stated Plaintiffs' position on the papers. It has not, however, caused the Court to revisit its ruling.

Facts and Procedural History

5. Plaintiffs are Dr. Goffney and his Southern California medical practice. Dr. Goffney has been a provider of medical services through Medicare since 1991. However, at some point in the 2000s and 2010s, his ability to obtain Medicare reimbursements got fouled up. Without delving into the details of this extensive history, Plaintiffs claim that they are entitled to several million dollars in unpaid reimbursements for services rendered on behalf of – and, they claim, bills submitted to – the Medicare system during that period of time.

6. Plaintiffs wisely concede for purposes of the motion that Dr. Goffney's Medicare account was deactivated for non-submission of claims at some point before 2015. (Docket # 46-1 at 21.) (Plaintiffs make clear that the current appeal to the district court does not address the propriety of the agency's deactivation of the account.)

7. At issue in this appeal is Dr. Goffney's most recent attempt to rectify the billing snafu. In mid-2015, Dr. Goffney sought to reactivate his billing privileges pursuant to 42 C.F.R. § 540(b)(2). That regulation states that a party whose account has been

"deactivated for nonsubmission of a claim" is required to "recertify" enrollment information already on file with Medicare.

8. Note – That's different from a Medicare deactivation for "any reason other than nonsubmission of a claim." This language comes from Section 424.540(b)(1) of the regs. The remedy for a 540(b)(1) deactivation: either "submit a new enrollment application" or, "when deemed appropriate[,] recertify" existing enrollment information with the agency.

***2** 9. So, in 2015 Dr. Goffney submitted Form CMS-855B.[1] (Docket # 26-2 at 81-82.) That's the multi-purpose form entitled "Medicare Enrollment Application." Multi-purpose? It's expressly intended to be used by "new enrollees" in the Medicare program or, in all likelihood, folks seeking to fix a Section 424.540(b)(1) deactivation. It also is used by previously-enrolled Medicare suppliers who (i) reactivate billing privileges, (ii) voluntarily terminate Medicare enrollment, (iii) change ownership or other significant information regarding their business, or (iv) periodically revalidate enrollment information. (Docket # 52 at 110.) The substantive information that the form user submits varies with the type of service covered by the "application." (*Id.* at 111-12.) On its

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[1] He may also have submitted Form CMS-855I (Docket # 51 at 6), although it doesn't appear in the administrative record. In the absence of an objection from the government, the Court takes judicial notice of the instructions to both blank forms that Plaintiffs submitted. (Docket #52 at 107-120.)

face, the form seems designed to cure a deactivation under Section 424.540(b)(2), too.

10. Dr. Goffney and his practice did not submit a full, new enrollee application for his practice. Instead, he checked the box seeking a revalidation of his existing Medicare enrollment. (Docket # 26-2 at 81-82.) (Why didn't he check the more applicable box for a reactivation of his dormant enrollment? No clue.)

11. The agency understood the purpose of the Goffney submission. According to the ALJ, the Medicare contractor "received an initial Medicare enrollment application from Petitioner. The contractor treated this application as an application by Petitioner to reactivate his billing privileges" and billing number. (Docket # 26-1 at 8 (emphasis added); # 26-1 at 11 (same conclusion by Departmental Appeals Board).)

12. Later in the ALJ's decision, though, the agency noted that its contractor had to pick an effective billing date for Dr. Goffney's reactivated Medicare account. The ALJ concurred with the contractor's analysis that Section 520(d) applied here. That provision sets the effective date for a physician's billing privileges as the later of "the date of filing of a Medicare enrollment application" or "the date that the supplier first began furnishing services" at a new location. For purposes of setting an effective date, then, the ALJ apparently considered Plaintiffs' 2015 "application for reactivation" to be the equivalent of an enrollment application under this regulation. (Docket # 26-1 at 9.)

13. The appeals board agreed. (Id. at 17.) On reconsideration, it affirmatively concluded that "the law governing the [ ] effective-date determination" for Plaintiffs' application "is 42 C.F.R. § 520(d)." (Docket # 26-1 at 24.) Further, Plaintiffs did "not argue that some other regulation or statute applies and authorizes a different effective date." As a result, the agency concluded that it "is bound by section 424.520(d) and has no authority to disregard or make exceptions to its applicability."[2] (Id.)

14. So, the date of the reactivation application became the effective date for Plaintiffs' account. That, in turn, led the agency to deny reimbursement for claims that preceded the 2015 paperwork. From Dr. Goffney's perspective, his earlier Medicare claims therefore remained unpaid.

The Parties' Contentions

***3** 15. Plaintiffs' central argument on appeal is straightforward. Plaintiffs contend that Sections 424.520 and 540 are "clear and unambiguous," and support his claim for an earlier effective billing date (and more reimbursement). (Docket # 51 at 7.) According to Plaintiffs, Dr. Goffney didn't submit an

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[2] It's not entirely clear from the parties' submissions whether this Court is to review the decision of the ALJ (as is typical in the Social Security disability benefits context) or those of the appeals board as the agency's final arbiter. Does it matter, though? The agency's appellate body affirmed the ALJ's decision twice, relying on the ALJ's interpretations of the evidence and the regulations, and did not materially change the basis for the adverse decision against Plaintiffs. To that end, the Court refers to the rather uniform conclusions of both administrative bodies.

enrollment application in 2015 – he submitted a reactivation application. And, because his limited submission was not a new enrollment application, the agency should never have applied the rule under Section 424.520(d) that looked to the date of the submission. Instead, Dr. Goffney contends that the agency should have reactivated his account, looked back to his original 1991 enrollment date, and allowed him to seek reimbursement for pre-reactivation claims.

16. The government argues that the agency's action in setting a 2015 effective billing date was correct and reasonable under the regulations. The government states that Section 424.520(d) "is the only regulation for establishing an effective date for physician billing privileges; there is not another regulation" addressing the submission of an application for reactivation of privileges." (Docket # 50 at 15.) The government contends that the agency's decisions addressing the relevant regulations are entitled to deference.

17. Additionally, the government points to a provision in the PIM – the Program Integrity Manual – that provides guidance to the agency and contractors in applying published regulations. PIM 15.27.1.2[3] advised Medicare contractors that an approved reactivation application should have an effective date of "the date the contractor received the application or [the package] was processed to completion." (Docket

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[3] Plaintiffs submitted an incomplete version of this material in the original appendix. (Docket # 47 at 41.) The full PIM regarding reactivations is at Docket 52 at 104-105.

50 at 15; # 52 at 105.) According to the government, these arguments support the 2015 effective date.[4]

Relevant Law and Analysis

18. The parties essentially agree on the standard of review for this action. Under 42 U.S.C. §§ 405(g) and 1395ff(b), decisions regarding Medicare benefits and payments are subject to limited judicial review in federal district court.[5] Heckler v. Ringer, 466 U.S. 602, 605 (1984) (same standard used in Social Security disability determinations applies to Medicare Act

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[4] Plaintiffs contend that a 2019 change to the PIM (15.17 and 15.27.1.2) expressly allows "retrospective billing" of the type that Dr. Goffney urgently desires. However, Plaintiffs fail to convincingly demonstrate that this interpretation has any meaning in the review of the agency's actions several years ago. Moreover, the government accurately notes that the PIM has limited potential application; there's only a minimal 30-day lookback provision for unpaid bills (barring natural disasters). (Docket # 50 at 18-19.) Dr. Goffney wants far more than that by this action.

[5] Section 405 / 1395 review of the agency's actions is Plaintiffs' exclusive appellate remedy here. Ringer, 466 U.S. at 614-15 ("sole avenue for judicial review" is under these provisions). Plaintiffs' attempt to seek review of the agency's actions pursuant to the Administrative Procedures Act [5 U.S.C. § 704 et seq.] is foreclosed. The APA provides "judicial review of final agency action for which there is no other adequate remedy in a court." Sackett v. EPA, 566 U.S. 120, 125 (2012) (quoting statute); Casa Colina Hospital v. Burwell, No. CV 15-3990 DSF (ASx) (C.D. Cal.), 2015 WL 11237100 (dismissing APA claim; Plaintiff failed to demonstrate that agency procedures or Section 405 review "would mean no review at all" of agency decision). To that end, the government does not appear to challenge Plaintiffs' contention (argued at some length at Docket # 46-1 at 15-18) that they have standing to pursue this case on appeal.

review); Pinnacle Peak Neurology, LLC v. Nordian Healthcare Solutions, LLC, 773 F. App'x 910 (9th Cir. 2019) (provider's claims for payment "arise under" Medicare Act). A district court must affirm the agency's denial of benefits unless the agency's findings are "based on legal error or are not supported by substantial evidence in the record." Lamear v. Berryhill, 865 F.3d 1201, 1204 (9th Cir. 2017); Conahan v. Sibelius, 659 F.3d 1246, 1249 (9th Cir. 2011) (same re: Medicare Act).

***4** 19. "Substantial evidence" is "such relevant evidence as a reasonable person might accept as adequate to support a conclusion." Biestek v. Berryhill, ___ U.S. ___, 139 S. Ct. 1148, 1154 (2019) (quotation omitted). The "threshold for such evidentiary sufficiency is not high"; however, it is "more than a mere scintilla" of proof. Id.

20. Error in a determination under Section 405 is subject to harmless error analysis. Ludwig v. Astrue, 681 F.3d 1047, 1054 (9th Cir. 2012); Hindley v. HHS, 2017 WL 1398257 at *5 (N.D. Cal. 2017) (Medicare Act); Gordian Medical, Inc. v. Sebelius, No. CV 10-3933 CAS (FFMx), 2012 WL 1155849 at *5 n.7 (C.D. Cal. 2012) (same). Error is harmless if "it is inconsequential to the ultimate [ ] determination" or, despite the legal error, "the agency's path may reasonably be discerned." Treichler v. Comm'r of Soc. Sec. Admin., 775 F.3d 1090, 1099 (9th Cir. 2014).

21. Federal courts will defer to an agency's reasonable reading of "genuinely ambiguous regulations." Kisor v. Wilkie, ___ U.S. ___, 139 S. Ct.

2400, 2408 (2019) (discussing deference under Auer v. Robbins, 519 U.S. 452 (1997)).[6] A regulation may be ambiguous if it does "not directly or clearly address every issue [or] when applied to some fact patterns." Id. at 2010 (Kagen, J., for plurality).

22. Per Kisor, a court must empty its "legal toolkit" to determine that a regulation truly is ambiguous. If so, the agency's interpretation and application of the regulation "must still be reasonable" in light of: the "character and context" of the agency's interpretation; the "authoritative" manner in which the interpretation came about; implications about the agency's "substantive experience"; and whether the agency's "fair and considered judgment" gave "fair warning" to parties or represented an "unfair surprise to regulated parties."[7] Id. at 2417-18.

23. An internal administrative publication such as the PIM "may be entitled to respect" on appellate review "to the extent that it provides a persuasive interpretation of an ambiguous regulation." However, the PIM (or its Social Security analogue, the "POMS") do "not impose judicially enforceable duties" on a

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[6] Auer deference (to agency interpretation of its regulations) differs from Chevron deference (agency interpretation of a federal statute giving rise to regulations). Plaintiffs confusingly point to Chevron deference rules as a relevant reviewing standard here. (Docket # 46-1 at 18-20.) It's not – Plaintiffs advance no colorable argument that an agency regulation is inconsistent with any act of Congress here.

[7] Kisor came down during the midst of the briefing on the motion. It is the Court's understanding that the recent Supreme Court's decision did not materially modify the analysis of Auer deference.

reviewing court. Carillo-Years v. Astrue, 671 F.3d 731, 735 (9th Cir. 2011) (quotations omitted).

* * *

24. At its core, Plaintiffs' complaint about how the agency construed his application has some facial merit. No evidence supports the conclusion that Dr. Goffney submitted a Medicare enrollment application for the purpose of establishing himself as a new enrollee in the program.

25. To the contrary, the contractor and the agency quite clearly understood that the 2015 submission was intended to reactivate his dormant / deactivated billing number. Indeed, the ALJ and the reviewing board expressly noted that the contractor wasn't swayed by the practitioner's mere use of the CMS form entitled "enrollment application" – in reality, it was "treated [ ] as an application by Petitioner to reactivate his billing privileges." (Docket # 26-1 at 8.) That's because Dr. Goffney made reasonably clear (by checking the revalidation box) what the purpose of the application was.

***5** 26. So, to the extent that the agency's fact-finder somehow equated the "reactivation" application with a new enrollment application, no evidence could plausibly support that determination.[8] A reasonable

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[8] The government suggests that Plaintiffs' submission of the catch-all form automatically invoked operation of Section 424.520(d). (Docket # 50 at 14 ("Dr. Goffney clearly supplied a form CMS-855 enrollment application, as opposed to some other type of form[.] Thus, § 424.520(d)(1) applied on that basis

person would not be convinced that the Goffney form should be construed in that manner. Biestek, 139 S. Ct. at 1154.

27. But any erroneous references in the administrative decisions to the nature of Plaintiffs' application are surely harmless. Ludwig, 681 F.3d at 1054; Treichler, 775 F.3d at 1099. A fair reading of the agency's rulings does not suggest that a flawed assessment of the paperwork (reactivation v. new enrollment application) led to an incorrect application of the agency's regulations. (Docket # 46-1 at 23 (Plaintiffs allege "it was an error for Defendant to have construed Plaintiffs' 2015 reactivation application as an enrollment application.").) The agency obviously and expressly knew the nature of the submission. Any error attributable to labelling the document as an "enrollment application" rather than a "reactivation application" was surely immaterial to the outcome below.

28. Rather, as the agency explained, its analysis turned on whether there was a regulatory command as to how to treat the reactivation papers. The agency concluded that Section 424.520(d) was the only appropriate regulation applicable to Plaintiffs' circumstance here. (Docket # 26-1 at 17, 24.) That's a

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alone.").) That argument is without any legal or evidentiary support. Moreover, what paper was Dr. Goffney supposed to use? No, the physician didn't waive anything or confuse the agency by using the wrong form here. He submitted a legitimate, multi-purpose form in an effort to turn his account back on, not to establish a new enrolled relationship with Medicare.

legal question, not a factual one. Any factual error here was harmless. Treichler, 775 F.3d at 1099.

* * *

29. Turning to Plaintiffs' key legal claim, then, are Sections 424.520 and 540 so clear that the agency committed legal error in setting the new Goffney activation date?

30. Section 424.540 is certainly an easy-to-understand provision. If a provider is deactivated, the reg gives two routes to rectify the problem. In Plaintiffs' circumstance, the deactivation due to nonsubmission of claims (540(b)(2)) requires a recertification regarding enrollment information. The regulation also explains that deactivation is intended for antifraud reasons – to protect a provider from misuse of its billing number and "to protect the Medicate Trust Funds from unnecessary overpayments." 42 C.F.R. § 424.540(c). Section 424.540 surely suggests that reactivation will lead to resumption of future Medicare payments for services rendered.

31. But there's a pretty obvious silence in the regs about whether a past "effective date" is warranted following reactivation. The agency itself stated that it found "no authority in the regulations for treating a deactivation" as if it were some other type of termination or revocation of billing privileges. (Docket # 26-1 at 18.) Neither did Plaintiffs. The agency also determined that Plaintiffs did not point to any other

controlling regulation that plausibly led to a different effective date for billing. (Id. at 24.)

***6** 32. Instead, the appellate board treated as settled that the "governing law on how CMS (and its Medicare contractors) determine the effective date for physicians applying for Medicare billing privileges is set by regulation" at Section 424.520(d). (Docket # 26-1 at 17.) That provision essentially led the agency to conclude that the date of filing of an application from the provider – be it for new enrollment or reactivation of an existing account – applied here. 42 C.F.R. § 424.520(d)(1).

33. The Court concludes that the agency's regulations are "genuinely ambiguous" in this area. Medicare frequently cuts off providers for lack of billing or failure to periodically recertify accounts. That's the whole purpose of Section 424.540, as well as the reason that Form CMS has the handy check-the-box method to request reactivation of an account. But the voluminous regulations do not "directly or clearly address [the] fact pattern[ ]" of when a reactivated account is, well, reactivated. Kisor, 139 S. Ct. at 2010. Instead, the agency here looked to the somewhat-analogous situation of establishing an effective billing date when a new enrollment application is submitted, pursuant to Section 424.520.

34. That's an agency decision entitled to Auer deference. The parties agree that no other regulatory provision is on point. It was therefore reasonable for the agency to look to the parallel, new enrollee rule (Section 424.520) in determining the reactivation date

here. The express purpose of deactivating dormant accounts is to reduce fraud against the federal fisc; that's what Section 424.540(c) flat-out states. In the context of Medicare regulations, it makes sense for the agency to decline to accept reimbursement requests before a closed billing number is validly reactivated – just as it would not accept pre-enrollment billing requests from a new provider. That's basic fraud prevention.

35. Moreover, there is nothing before the Court to suggest any unfair surprise by the agency's assertion that a physician must have an active, valid billing number in place in order to obtain reimbursement from the Medicare system. That's the plain takeaway from Section 424.520 (new folks need a valid enrollment on file) and Section 424.540 (we deactivate dormant numbers to protect against "unnecessary overpayments"). It's also strongly suggested by the PIM provision directing Medicare contractors to look to the date when the provider sends in a "reactivation certification package" as the "reactivation effective date." (Docket # 47 at 42.) That's a "persuasive interpretation" of the regulations at issue here, and is worthy of "respect" on appellate review. Carillo-Years, 671 F.3d at 735. Under Kisor and Auer, the agency provided a reasonable basis for applying the Section 424.520 effective date to Plaintiffs' circumstance.

36. Plaintiffs offer a series of challenges and objections to the agency's actions; they don't get too far. Plaintiffs contend that they were not required to submit a new enrollment application to the agency in order to reactivate the Goffney account. (Docket # 46-1 at 21-23.) Yet, as noted above, the agency's decisions

make reasonably clear that it understood the nature of Plaintiffs' reactivation request.

37. Further, Plaintiffs argue that a new effective date irreparably affects the participation agreement and conditions of participation in Medicare. (Docket # 46-1 at 26.) That argument is utterly conclusory and without any articulated support. It also contradicts the logic of the Medicare payment system (incorporated into both Sections 424.520 and 540): providers agree to bill for services when they have an active enrollment in the system.

* * *

***7** 38. At bottom, the Court generally agrees with Plaintiffs on a key point – there's no clear regulation stating when a reactivated account regains billing privileges. The government and the agency's decisions concede this too. But the agency did not act unreasonably in using the date that Plaintiffs filed the paperwork as the date of resumption for billing. The agency's reasonable interpretation of its regulatory scheme is entitled to deference. As a result, the decision setting the 2015 effective date should be affirmed.

39. A separate judgment will issue.

APPENDIX D

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD,
Appellate Division.

Docket No. A-17-67
Ruling No. 2017-5
September 15, 2017

WILLIE GOFFNEY, JR., M.D.,
Petitioner.

RULING ON PETITION TO REOPEN
DEAPARTMENTAL APPEALS BOARD
DECISION 2763

Before Hegy, Tobias, and Sussan, Board Members.

On March 23, 2017, Willie Goffney, Jr., M.D. (Petitioner) submitted a petition to reopen Board Decision No. 2763 (Jan. 23, 2017). We deny the petition because it identifies no error of fact or law in the Board's decision.

Reopening under 42 C.F.R. Part 498

Title 42 C.F.R. § 498.100 authorizes the Board, on its own motion or at the request of either party, to reopen a decision within 60 days of the date of notice of the decision. Section 498.100 does not specify circumstances in which the Board may or must reopen a decision.[1] In appeals under 45 C.F.R. Part 16, the Board may "reconsider" a decision when a party "promptly alleges a *clear error* of fact or law." 45 C.F.R. § 16.13 (italics added). The Board has held that this clear-error standard is "reasonably applied" in deciding whether to reopen a decision in an appeal brought under 42 C.F.R. Part 498. *Experts Are Us, Inc.,* DAB No. 2342, at 2 (2010). The Board has emphasized that reopening a decision is not a routine step in the administrative appeal process but, rather, an opportunity for the parties to identify "any errors that make the decision clearly wrong." *Id.; see also Peter McCambridge, C F.A.,* DAB Ruling No. 2010-1, at 1 (Feb. 2, 2010); *BioniCare Medical Technologies, Inc.,* DAB Ruling No. 2011-3, at 1 (Dec. 2, 2010).

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[1] Title 42 C.F.R. § 498.102, titled "Revision of reopened decision," implies that the Board may reopen its decision to consider "new evidence." However, "[t]he Board generally will not exercise the discretion to reopen based on evidence that a party could have submitted before, but did not." *Meadowwood Nursing Ctr.,* DAB Ruling No. 2014-1, at 5 (March 12, 2014). (All cited rulings are available on the Board Decisions webpage at https://www.hhs.gov/about/agencies/dab/decisions/board-decisions/board-decisions-by-year/index.html.)

Case Background

Sometime between 2005 and 2012 – precisely when is unclear – CMS deactivated Petitioner's Medicare billing privileges on the ground that he had failed to submit a Medicare payment claim for twelve consecutive months. *See* DAB No. 2763, at 2-3, 4 n.3 (discussing 2012 correspondence from CMS stating that deactivation occurred in 2008); Pet. to Reopen at 2 (asserting that CMS "deactivated Petitioner's account" in "approximately" 2005).

On August 31, 2015 seeking to reactivate his billing privileges, Petitioner filed a Medicare enrollment application, which CMS evidently treated as an "initial" application for enrollment. *See* Pet. to Reopen at 3; DAB No. 2763, at 1, 6, 7; CMS Exs. 1-2 (Civil Remedies Division (CRD) Docket No. C-16-365). CMS approved the application and granted him billing privileges effective August 31, 2015. CMS Ex. 2, at 1 (CRD Docket No. C-16-365). Petitioner appealed that decision, contending that his billing privileges had been improperly deactivated (or deactivated without adequate notice or opportunity for "rebuttal") and that CMS should therefore have granted him billing privileges retroactive to 1991. DAB No. 2763, at 2, 8. An administrative law judge (ALJ) granted summary judgment to CMS, and the Board affirmed the ALJ's decision. *Id.* at 1, 7.

The Board's Decision

Addressing Petitioner's allegation that his Medicare billing privileges had been improperly deactivated, the Board held that neither the administrative appeal regulations in 42 C.F.R. Part 498, nor the Medicare enrollment regulations in 42 C.F.R. Part 424, authorize the Board or its ALJs to review a deactivation decision by CMS or its contractors. DAB No. 2763, at 3-5. The Board further noted that, in Petitioner's circumstances, the Part 498 regulations authorized it to decide only whether CMS had correctly set the effective date based on the enrollment application he filed on August 30, 2015. *Id.* at 5. Given that limitation on the scope of review, the Board held that issues or claims arising from Petitioner's interaction or relationship with CMS and the Medicare program prior to August 30, 2015 were "not material." *Id.* at 4.

Title 42 C.F.R. § 424.520(d) states in relevant part that the "effective date for billing privileges" is "*[t]he date of filing* of a Medicare enrollment application that was subsequently approved by a Medicare contractor" (italics added). Applying that regulation, the Board held that the pertinent "date of filing" - and hence Petitioner's effective date – was August 31, 2015. DAB No. 2763, at 3-5. The Board rejected Petitioner's suggestion that he was entitled to an earlier effective date because CMS had earlier (that is, prior to August 2015) somehow misled him about his status in the Medicare

program. *Id.* at 8 (noting that Petitioner did not show that the "ALJ or the Board has any authority to alter an effective date for equitable reasons, even had he shown that affirmative misconduct occurred, which he has not on this record"). Finally, the Board held that it had no authority to resolve disputes relating to his eligibility for, or the denial of, Medicare payment for services he furnished during or prior to the deactivation period. *Id.* at 6.

The Petition to Reopen

Petitioner asks us to reopen the Board's January 23, 2017 decision based on "new and material evidence" that was not included in the record of that decision. Pet. to Reopen at 2. That "evidence," more accurately described as documentation of law and CMS policy governing Medicare enrollment, consists of two exhibits (A and B) attached to the petition to reopen. Exhibit A is a copy of the April 21, 2006 Final Rule, as published in the *Federal Register,* adopting the Medicare enrollment regulations in 42 C.F.R. Part 424, subpart P. As relevant to Petitioner's argument, section 424.515 of the enrollment regulations requires a provider or supplier to periodically "'revalidate" – that is, "recertify the accuracy" of – its "enrollment information" on file with the Medicare program in order "[t]o maintain Medicare billing privileges." 42 C.F.R. § 424.515. That section also states that "CMS contacts each provider or supplier directly when it is time to revalidate . . . enrollment information." *Id.* § 424.515(a)(l). Exhibit B to the petition to reopen

is a "Model Revalidation Letter" published in section 15.24.5 of CMS's Medicare Program Integrity Manual. The letter notifies a provider or supplier of its obligation to revalidate its enrollment information every five years and requests that it do so within 60 days of the postmarked date of the letter.

Relying on these exhibits, Petitioner contends that, prior to August 30, 2015, he "never received" notice from CMS to revalidate his enrollment. Pet. to Reopen at 6, 8. He suggests that CMS should have sent him a notice to "revalidate" in mid-2008. *Id.* at 6 n.l. Had CMS done so, says Petitioner, he would "have had the opportunity to timely revalidate his account and maintain his original 1991 effective date for billing privileges." *Id.* at 10-11. Petitioner asks the Board to "consider whether, pursuant to the regulations and policies governing the requirements for notice of CMS'[s] requirements to recertify or to re-validate an existing provider or supplier account under the new rules [promulgated in April 2006], a failure to notify the provider or supplier is a denial of due process." *Id.* at 7. Petitioner asserts – though without any supporting legal analysis – that CMS's "failure to provide notice of the requirements for revalidation . . . is an issue wholly intertwined with the effective date determined in the ALJ decision." *Id.* at 7-8.

Discussion

Elements of Petitioner' s argument are speculative or unclear. For example, Petitioner fails to explain how receipt of a revalidation notice in mid-2008 would have – under then-current rules – enabled him to "maintain his original 1991 effective date" given that CMS had likely deactivated his billing privileges before then. *See* Pet. to Reopen at 3, 6 n.1 (alleging that deactivation occurred in 2005). Petitioner also has not explained why it would be legally sound to read section 424.515 as requiring CMS to send revalidation notices to physicians whose billing privileges are no longer active when, as noted, the revalidation process enables those who *have* billing privileges to "maintain" them. Nor, even if Petitioner's reading were correct, has he pointed to any connection in the regulations between a failure by CMS to send a revalidation notice and the limited appeal rights granted under the regulations. In addition, Petitioner's claim of prejudice is unconvincing. While we understand that a revalidation notice might have alerted Petitioner to inquire about, and apply to restore, his billing privileges earlier than August 2015, he does not identify any circumstances that prevented him from taking that action on his own initiative.

We need not pursue these issues further or decide the merits of Petitioner's so-called "due process" claim – which, we note, alleges no procedural defect in the underlying hearing and appeal process. The only issue before us now is whether Petitioner has

identified a prejudicial legal or factual error in the Board's decision. He has not done so.

As outlined above, the result in Board Decision 2763 rested on four holdings:

- Under the applicable administrative appeal regulations in 42 C.F.R. Part 498, the Board was authorized to decide only whether CMS had properly determined the effective date for Medicare billing privileges based on Petitioner's August 31, 2015 enrollment application[2];

- Given the limited scope of review, "contentions about events and interactions other than [Petitioner's] August 31 2015 application" were "not material" to the outcome of the appeal[3];

- The law governing the appealable effective date determination is 42 C.F.R.

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[2] DAB No. 2763, at 5 (stating that "[t]he only action in the reconsidered determination which is appealable [to an administrative law judge and then the Board] is thus the initial determination of the *effective date of the enrollment application* reinstating Petitioner" (italics added)); *id* at 7 (stating that the Board's "decision resolves only when the billing privileges granted based on the application filed on August 31, 2015 became effective").

[3] DAB No. 2763, at 4.

§ 424.520(d)[4]; and

- CMS correctly determined under section 424.520(d) that August 31, 2015 was the effective date for Medicare billing privileges based on the enrollment application filed by Petitioner on August 31, 2015 and subsequently approved by CMS.[5]

Petitioner does not contend that any of these holdings is erroneous, much less clearly erroneous. He does not, for example, argue that the Board improperly described the scope of its review, made unsound relevance or materiality findings, or misconstrued or misapplied section 424.520(d); Petitioner merely makes a new purported legal claim arising from his pre-August 31, 2015 relationship with the Medicare program. Nor does Petitioner explain why he could not have made this legal argument in the prior proceeding since the regulatory changes on which he relies were effective at that time. The purpose of the reopening authority in section 16.13 is to enable the Board to correct any clear errors it makes in its decisions, not

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[4] DAB No. 2763, at 7 (explaining that "[t]he governing law on how CMS (and its Medicare contractors) determine the effective date for physicians applying for Medicare billing privileges is set by" section 424.520(d)).

[5] DAB No. 2763, at 7.

to give litigants an opportunity to make new arguments.

Like his claim that his billing privileges were improperly deactivated, Petitioner's contention that he was never notified of his obligation to revalidate his billing privileges has no bearing on the legality of the effective-date determination that he appealed to the ALJ and the Board. That determination, as the Board held, is governed by section 424.520(d), which requires that a supplier's effective date be either the "date of filing" of an enrollment application "subsequently approved" by CMS or, if applicable, "[t]he date that the supplier first began furnishing services at a new practice location." No other "date" is mentioned in section 424.520(d), and Petitioner does not argue that some other regulation or statute applies and authorizes a different effective date. As an administrative tribunal, the Board is bound by section 424.520(d) and has no authority to disregard or make exceptions to its applicability. *Vijendra Dave, M.D.,* DAB No. 2672, at 8 (2016); *see also Oaks of Mid City Nursing and Rehab. Ctr.,* DAB No. 2375, at 30-31 (2011) (stating that the Board may not fail to follow a clearly applicable regulation).

Conclusion

The Petitioner having failed to identify a prejudicial error of fact or law in Board Decision 2763, we deny his March 23, 2017 petition to reopen.

s/Sheila Ann Hegy
Sheila Ann Hegy

s/Constance B. Tobias
Constance B. Tobias

s/Leslie A. Sussan
Leslie A. Sussan

APPENDIX E

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD,
Appellate Division

Docket No. A-16-121
Decision No. 2763
January 23, 2017

WILLIE GOFFNEY, JR., M.D.
Petitioner.

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Before Hegy, Tobias, and Sussan, Board Members.

Willie Goffney, Jr., M.D. (Petitioner) timely appealed the decision of an Administrative Law Judge (ALJ) upholding the determination of the Centers for Medicaid & Medicare Services (CMS) that the effective date for reactivation of Petitioner's Medicare billing privileges was August 31, 2015. *Willie Goffney, Jr., M.D.,* DAB CR4619

(2016) (ALJ Decision). The ALJ concluded that no material facts relevant to the correctness of the effective date were in dispute, and that those facts which Petitioner did contest related only to the deactivation of his billing privileges – an action which the ALJ determined was not within his jurisdiction. Accordingly, the ALJ granted summary judgment in favor of CMS upholding the effective date.

For the reasons explained below, we conclude that CMS determined the effective date as required by the applicable law and that the ALJ correctly determined that the other issues which Petitioner sought to inject cannot properly be addressed in this proceeding. We therefore uphold the ALJ Decision.

Background

Before the ALJ, CMS sought summary judgment on the ground that the following facts established as a matter of law that August 31, 2015 was the earliest possible effective date for Petitioner's reactivation:

> On October 31, 2012, a Medicare contractor notified Petitioner that his provider transaction access number (PTAN) was deactivated on the ground that Petitioner had not filed Medicare reimbursement claims since 2008. P. Ex. 5; *see* Ex. 3 to Petitioner's Hearing Request; *see* CMS Ex. 4.

> On August 31, 2015, a Medicare contractor received an initial Medicare enrollment application from Petitioner. The contractor treated this application as an application by Petitioner to reactivate his billing privileges and PTAN. CMS Ex. 1.
>
> On October 2, 2015, the contractor advised Petitioner that his application was approved and that he was assigned an effective billing date of August 31, 2015. CMS Ex. 2.

ALJ Decision at 2. Petitioner sought reconsideration by the contractor and received an unfavorable reconsidered determination on December 18, 2015. CMS Exs. 3-4.

Petitioner's core contention is that either he was not, or at any rate should not have been, deactivated because he never went 12 months without submitting a claim (although apparently he has not been able to receive reimbursement since at least 2008). Therefore he contends, nothing should have "disrupt[ed] the flow of Petitioner's constant enrollment in Medicare since 1991." Petitioner's Request for Review (RR) at 4. On that theory, he argues that his "earliest effective enrollment date should be September 6, 1991." *Id.* According to Petitioner, his claims were rejected beginning in 2005 for reasons he does not understand. *Id.* at 1; *see also* CMS Ex. 1 (August 28, 2015 letter from Petitioner to CMS asking for expedited handling of his revalidation application because his "status with Medicare was inexplicably

changed many years ago" and he had not been paid for provided services). Moreover, he states that repeated inquiries to the contractor yielded various conflicting explanations, mostly relating to glitches in the transition to an electronic claims system. RR at 1-2, citing P. Exs. 8-9, 11-13. He asserts that, even after issuance of the deactivation letter in 2012, various contractor staff assured him that he had not been deactivated. *Id.*

The Board has previously explained the deactivation process as follows:

> Deactivation of a provider's or supplier's billing privileges is to be distinguished from denial of enrollment of a provider or supplier. "Deactivate" is defined to mean that "the provider or supplier's billing privileges were stopped, but can be restored upon the submission of updated information." *Id.* § 424.502. Medicare may deactivate an enrolled provider's or supplier's billing privileges for the reasons cited in 42 C.F.R. § 424.540(a), one of which is that the provider or supplier has not submitted any Medicare claims for 12 consecutive months, from "the 1st day of the 1st month without a claims submission through the last day of the 12th month without a submitted claim." *Id.* § 424.540(a)(l). "Deactivation of Medicare billing privileges is considered an action to protect the provider or supplier from misuse of its billing number and to protect the

Medicare Trust Funds from unnecessary overpayments." *Id.* § 424.540(c); *see also* Final Rule, 77 Fed. Reg. 29,002, 29,010 (May 16, 2012) (explaining that the purpose of deactivating a provider's or supplier's billing privileges for non-submission of claims for 12 consecutive months in accordance with section 424.540(a)(l) is "to prevent situations in which unused, idle Medicare billing numbers could be accessed by individuals and entities to submit false claims").

The regulations also permit CMS to ask a provider or supplier . . . to periodically "resubmit and recertify the accuracy of its enrollment information" in order to maintain billing privileges. 42 C.F.R. § 424.515. A provider or supplier whose billing privileges were deactivated for non-submission of a claim for 12 consecutive months is "required to recertify that the enrollment information currently on file with Medicare is correct and furnish any missing information as appropriate . . . [and] must meet all current Medicare requirements in place at the time of reactivation, and be prepared to submit a valid Medicare claim." *Id.* § 424.540(b)(2). *See also* 77 Fed. Reg. at 29,010 (stating that, in general, the recertification process entails "the submission of a completed CMS-855 enrollment application").

Deann Worthington, N.P., DAB No. 266l, at 2-3 (2015). Deactivation also differs from revocation in several ways, particularly in that revocation terminates a Medicare provider or supplier agreement and requires imposition of a re-enrollment bar of at least one year, neither of which occurs with deactivation. *Compare* 42 C.F.R. § 424.535(a), (b), (c) with § 424.540(c).

The provisions on supplier appeal rights also distinguish between denial or revocation of enrollment, which may be appealed under 42 C.F.R. Part 498, and deactivation, for which the supplier "may file a rebuttal in accordance with § 405.374." 42 C.F.R. § 424.545(a), (b). Section 405.374 simply permits the supplier "to submit any statement (to include any pertinent information) as to why [the deactivation] should not be put into effect on the date specified in the notice" to the contractor, generally within 15 days or less. *Id.* § 405.374(a).

Analysis

A. *Deactivation is not appealable and is not reviewable in this proceeding.*

Petitioner has not denied, before the ALJ or on appeal, that he received the letter notifying him of deactivation in 2012.[1] Nor does he assert that he

[1] The contractor sent this October 31, 2012 letter (P. Ex. 5) in response to a September 27, 2012 inquiry from Petitioner (P. Ex. 4) about why Medicare "continues to deny payment"

sought to file a rebuttal in response to that notice.[2] He contends, instead, that he is not trying to challenge the validity of a deactivation action but rather offering evidence to establish that his PTAN was never actually deactivated, or at any rate not properly deactivated for the reasons set out in the deactivation letter. RR at 1. He relies on these contentions to suggest that somehow the effective date of the action on his 2015 enrollment application should relate back to his original enrollment in Medicare. *Id.* at 3-4.

He bases his contentions about his deactivation on an account of his interactions with various individuals at the Medicare contractor in the years since 2005 when he asserts he stopped receiving payment for claims submitted to Medicare despite having been enrolled since

1991. *See* Petitioner's Affidavit (P. Aff.) at 2-5, and exhibits cited therein. He also provides a

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for his claims. The contractor explained that Petitioner's PTAN number "has been deactivated for non-billing since 2008." P. Ex. 5. Petitioner argues that the letter was wrong but not that he did not receive the letter.

[2] The record contains a letter dated September 23, 2013 in which Petitioner says that he believes there has been an error in his deactivation for nonbilling and asks for information. P. Ex. 6. He has not indicated that this submission in fact constituted a rebuttal, which would have been due l5 days after the deactivation notice, although at times he suggests that he should be viewed as having done what he could to respond to the notice which he came to believe was erroneous. *See* P. Reply at 5-6.

letter he wrote to the contractor in January 2006 saying he had learned of a "hold" on his account. P. Ex. 3. His affidavit refers to other "correspondence . . . by mail, email and phone" with the contractors after that, but he provides no examples or details of other communications before the inquiry that triggered the October 31, 2012 deactivation notice. P. Aff. at 2. Given this spotty record and multiple inconsistencies in those documents provided,[3] it is not possible to discern exactly when and why Petitioner's claims first began to be denied. It is also unnecessary that we do so.

Petitioner's contentions about events and interactions other than his August 31, 2015 application to reactivate his Medicare billing privileges are not material to this case. As the ALJ explained, the regulations do not provide a right to ALJ review of deactivation of billing privileges. Before an ALJ (or the Board) may review the correctness of an effective date determination, the provider must have sought, and the contractor must have issued, a reconsideration decision. That decision sets the

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[3] For example, Petitioner has variously asserted that he began receiving Medicare payments in l989 and 1991 (compare P. Ex. 1, at 1 and RR at 4 with P. Ex. 4) and that he ceased receiving them in 2005 or 2006 (compare P. Ex. 3 with Feb. 18, 2016 Reg. for Hearing). The October 31, 2012 notice indicates that he was deactivated in 2008 as a result of nonbilling but does not indicate when the period of nonbilling began or whether any billing was attempted thereafter.

parameters of the issues before the ALJ (and the Board) which are reviewable under the regulations. *Cf. Vijendra Dave, M.D.,* DAB No. 2672, at 8 n.10 (2016) (holding, in an appeal challenging a Medicare enrollment revocation, that the Board is "limited to reviewing the basis for revocation articulated in the unfavorable reconsidered determination issued by CMS or its contractor"). The regulations provide for appeal rights to an ALJ and then Board review only from certain specified "initial determinations" by CMS. 42 C.F.R. § 498.3(b). These appealable determinations include unfavorable reconsiderations as to:

> (15) The effective date of a Medicare provider agreement or supplier approval.
> * * *
> (17) Whether to deny or revoke a provider or supplier's Medicare enrollment in accordance with §424.530 or §424.535 of this chapter.

Id. The reconsidered determination on which our jurisdiction is based does not deny or revoke Petitioner's enrollment. CMS Ex. 4. The only action in the reconsidered determination which is appealable is thus the initial determination of the effective date of the enrollment application reinstating Petitioner.

Our conclusion in this regard is reinforced by a review of 42 C.F.R. § 424.545, which, as we have noted, spells out the appeal right of Medicare suppliers. Section 424.545(a) explains that a prospective supplier denied enrollment or an existing supplier whose enrollment has been revoked may appeal under the provisions of 42 C.F.R. Part 498. Section 424.545(b), by contrast, states only that a "supplier whose billing privileges are deactivated may file a rebuttal." A rebuttal is not itself an appeal. *See* 42 C.F.R. § 405.374 (defining "Opportunity for rebuttal" as "an opportunity to submit a statement . . ."). Moreover, neither section 424.545(b) nor any other regulation provides appeal rights from the contractor's deactivation determination or any rebuttal determination. *See also Arkady B. Stern, M.D.,* DAB No. 2417, at 3 n.4 (2011) (Petitioner argues on appeal that deactivation was improper, but Board "does not have authority to review" deactivation under circumstances of this case citing 42 C.F.R. §§ 424.545(b) and 498.3(b)); *Andrew J. Elliott, M.D.,* DAB No. 2334, at 4 n.4 (2010) (Board "does not have authority to review" a deactivation).

Moreover, despite his claims to the contrary, much of Petitioner's argument is indeed a challenge to the validity of his deactivation given his assertion that the October 31, 2012 letter provides a reason for deactivating that is "false and inapplicable" because he denies that he ever went twelve months without submitting a claim. RR at 2. Petitioner reasons that the flaws he sees in the deactivation letter demonstrate that the letter was issued "in error" and that his PTAN was therefore not deactivated.

Id. Whether the letter was issued due to some kind of error or was based on some misunderstanding regarding the status of Petitioner's PTAN or Petitioner's claiming practices does not alter either the letter's effect in providing notice of the deactivation of Petitioner's billing privileges, or the fact that deactivation is not an appealable initial determination.

B. *We do not have authority to review retrospectively the status of Petitioner's billing privileges or of Medicare claims from prior years that were either denied or never submitted.*

Even assuming Petitioner is not attempting to obtain a belated and unauthorized appeal of the 2012 deactivation letter, we still could not give Petitioner any of the review he seeks. Petitioner asserts a number of factual issues that appear to be designed to have the Board opine on the state of Petitioner's Medicare billing privileges. The Board has no authority to do this apart from reviewing the effective date set in the appealable determination (i.e., the December 18, 2015 reconsidered determination) on the August 31, 2015 enrollment application. In any event, determining the effective date of Petitioner's billing privileges based on the approval of this application does not determine whether he previously participated in Medicare or previously had a valid PTAN. Those questions, however important they may be to Petitioner, are not within our jurisdiction.

Beyond that, Petitioner's apparent underlying concern is that he wishes to receive reimbursement for services provided in prior years for which he either did not submit claims or for which his claims were denied. It is certainly true that he may not receive payment for claims for services during any period when his billing privileges were deactivated. Section 424.555(b) provides:

> No 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, denied, or revoked. The Medicare beneficiary has no financial responsibility for expenses, and the provider or supplier must refund on a timely basis to the Medicare beneficiary any amounts collected from the Medicare beneficiary for these otherwise Medicare covered items or services.

42 C.F.R. § 424.535(b). Disputes about Medicare claim reimbursement are not cognizable in this forum, however. Denial of Medicare reimbursement may be appealed only after submitting a claim and only through the process set out in 42 C.F.R. Part 405.. *See Vijendra Dave, M.D.* at 12.

Petitioner asserts that "the overwhelming evidence suggests that [the contractor] did not deactivate Petitioner's PTAN, but rather denied his claims because of an internal error." RR at 4. As with the

question of whether the deactivation took place or was well- founded, the questions of if and why any of Petitioner's claims were denied is beyond the scope of this proceeding, however consequential they may be to Petitioner.

Petitioner contends that the ALJ erred by resolving this case on summary judgment when "outcome-determinative questions of material fact" remained in dispute. P. Reply Br. at 4. None of the facts to which Petitioner refers, however, are material to the sole issue before the ALJ. For example, Petitioner contends that CMS relied on the deactivation as the reason that September 9, 1991 "is no longer" a valid effective billing date. *Id.* But we need not, and cannot, make conclusions as to whether Petitioner was deactivated properly or when, or as to whether his billing privileges first became effective on September 9, 1991. As we have explained, this decision resolves only when the billing privileges granted based on the application filed on August 31, 2015 became effective.

C. *The effective date set in the reconsideration decision is correct.*

Only facts relevant to the effective date resulting from the August 31, 2015 application were material to the ALJ Decision. The governing law on how CMS (and its Medicare contractors) determine the effective date for physicians applying for Medicare billing privileges is set by regulation as follows:

> The effective date for billing privileges for physicians . . . 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 [an enrolled physician] . . . first began furnishing services at a new practice location.

42 C.F.R. § 424.520(d). The date on which the approved application was filed was August 31, 2015, and Petitioner asserts he had long been providing services at the same practice location. *See* RR at 3-4. Therefore, as the ALJ correctly concluded, the only date on which billing privileges arising from the approved application could become effective is August 31, 2015.

We therefore find no error in the ALJ's decision to proceed by summary judgment.

D. *Petitioner's other legal arguments have no merit.*

We note that several arguments made in Petitioner's reply brief were not clearly articulated in his prior submissions. Generally, the Board will not consider issues which were not raised in the request for review or which could have been presented to the ALJ but were not. *See Guidelines – Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's or Supplier's Enrollment in the Medicare Program,* "Completion of the Review Process" (available at

https://www.hhs.gov/about/agencies/dab/differrent-appeals-at-dab/appeals-to-board/guidelines/enrollment/index.html); *John M Shimko, D.P.M.,* DAB No. 2689, at 11 (2016). Because Petitioner's contentions throughout have been less than entirely clear and have reflected confusion about the scope of the proceeding, we will nevertheless briefly explain why these arguments, even as they are now phrased, have no merit.[4] Petitioner now acknowledges that deactivation is not an initial determination giving rise to appeal rights, but suggests that, if the effective date here is upheld, his deactivation becomes "permanent" and somehow converts into an appealable revocation. P. Reply at 8. Moreover, he argues that, if CMS did deactivate his PTAN, it did so in violation of various regulations that he reads as requiring sufficient notice and opportunity to submit a rebuttal, or else the deactivation should become appealable as a revocation. *Id.* at 6-7. In support of these concepts, Petitioner cites only the 2011 decision of another ALJ in *Horatio Aldredge, M.D., et al.,* DAB CR2351 (2011), which was never appealed to the Board. The ALJ in *Aldredge* dismissed the hearing requests because the petitioners had no right to a hearing on their deactivation. *Id.* at l. In dicta, however, the ALJ opined as follows:

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[4] We also note that, while we have not responded to every formulation of Petitioner's contentions, we have fully considered all arguments that appear to be raised on appeal, regardless of whether our decision contains a detailed written analysis of each.

> Although I dismiss this case, it is my hope that the contractor will properly address Petitioners' concerns about an improper deactivation through the rebuttal process. If CMS does not properly address Petitioners deactivations through the regulatory process, Petitioners may file a request to vacate this dismissal within 60 days, pursuant 42 C.F.R. § 498.72. I will then consider the issue of whether CMS has, in effect, improperly revoked Petitioners' billing privileges as opposed to deactivating them.

Id. at 5-6. There is no record of whether any of the petitioners in *Aldredge* did file rebuttals or of what action CMS took, but we find no indication that the dismissal was ever in fact vacated. Moreover, we find no authority in the regulations for treating a deactivation as if it were a revocation. An ALJ decision is not itself precedent or binding on the Board, and the ALJ decision which Petitioner cites merely suggests that the ALJ issuing it might consider such an argument in the event the matter returned to him in a motion to vacate his dismissal.

Finally, we reject Petitioner's claims that the ALJ could or should have offered him some form of equitable relief. The ALJ concluded that, to the extent that Petitioner's complaints about the contractor amounted to a request for equitable relief, he did not have authority to consider such a request. ALJ Decision at 4, citing *US Ultrasound,* DAB No. 2302, at 8 (2010). Petitioner argues that

the information he c1aims to have received from contractor employees was so misleading as to constitute misconduct (RR at 6), relying on cases in which the Board (and courts) have said that the equitable remedy of estoppel could lie against the government, if at all, only in the situation of affirmative governmental misconduct. *See, e.g., Illinois Dep't of Children & Family Servs.,* DAB No. 2734, at 8 (2016) (government cannot be estopped "absent, at a minimum, a showing that the traditional requirements for estoppel are present . . . and that the government's employees or agents engaged in 'affirmative misconduct'") citing *Office of Pers. Mgmt. v. Richmond,* 496 U.S. 414, 421 (1990). Petitioner has not shown that the ALJ or the Board has any authority to alter an effective date for equitable reasons, even had he shown that affirmative misconduct occurred, which he has not on this record.

Conclusion

For the reasons fully explained above, we sustain the ALJ Decision and uphold the effective date as determined by CMS.

s/Sheila Ann Hegy
Sheila Ann Hegy

s/Constance B. Tobias
Constance B. Tobias

s/Leslie A. Sussan
Leslie A. Sussan

APPENDIX F

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD,
Civil Remedies Division

WILLIE GOFFNEY, JR., M.D.
Petitioner,

v.

CENTERS FOR MEDICARE & MEDICAID SERVICES,
Respondent.

Docket No. C-16-365
Decision No. CR4619
May 26, 2016

DECISION

Before Kessel, Administrative Law Judge.

I grant summary judgment sustaining the determination of a Medicare contractor, as affirmed

upon reconsideration and ratified by the Centers for Medicare & Medicaid Services (CMS), establishing an effective date of August 31, 2015, of reactivation of Medicare billing privileges for Petitioner Willie Goffney, Jr., M.D.

I. Background

Petitioner, a physician, requested a hearing in order to challenge the effective date of reactivation of Petitioner's Medicare billing privileges. CMS moved for summary judgment, filing a brief and four exhibits that are identified as CMS Ex. 1-CMS Ex. 4. Petitioner filed a brief in opposition and 12 exhibits that are identified as P. Ex. 1-P. Ex. 12. Petitioner also filed an affidavit, and I have identified it as P. Ex. 13. I receive these exhibits into the record for purposes of ruling on CMS's motion.

II. Issue, Findings of Fact and Conclusions of Law

A. Issue

The issue is whether a Medicare contractor properly determined August 31, 2015, to be the effective date of reactivation of Petitioner's Medicare billing privileges.

B. Findings of Fact and Conclusions of Law

In support of its motion CMS relies on the following facts:

- On October 31, 2012, a Medicare contractor notified Petitioner that his provider transaction access number (PTAN) was deactivated on the ground that Petitioner had not filed Medicare reimbursement claims since 2008. P. Ex. 5; *see* Ex. 3 to Petitioner's Hearing Request; *see* CMS Ex. 4.

- On August 31, 2015, a Medicare contractor received an initial Medicare enrollment application from Petitioner. The contractor treated this application as an application by Petitioner to reactivate his billing privileges and PTAN. CMS Ex. 1.

- On October 2, 2015, the contractor advised Petitioner that his application was approved and that he was assigned an effective billing date of August 31, 2015. CMS Ex. 2.

CMS contends that these facts are both undisputed and that they establish that, as a matter of law, Petitioner was assigned a correct reactivation date. Petitioner contends that the facts are very much in dispute. I disagree. The essential facts cited by CMS are undisputed and, as CMS asserts, they

establish that the effective reactivation date assigned to Petitioner is correct as a matter of law.

What is certainly undisputed is that a contractor notified Petitioner on October 31, 2012, that Petitioner's PTAN was deactivated. Petitioner's only recourse from that action was to file a request to have his PTAN reactivated. *Arkady B. Stern, M.D.,* DAB No. 2329, at 4 n.5 (2010) (citing Medicare Program Integrity Manual (MPIM) Rev. 289, issued April 15, 2009, effective January 1, 2009); *see also* MPIM, Chapter 15, Section 15.27.1.2.3, effective October 8, 2013. Petitioner had no right to challenge the provider's action via a hearing request inasmuch as that action is not an initial determination that gives rise to hearing rights. 42 C.F.R. §§ 498.3, 498.5(1). Thus, I may not consider any arguments from Petitioner concerning the propriety of the contractor's action in deactivating his PTAN.

Given that, the only question I may consider is whether the contractor properly assigned Petitioner an effective reactivation date of August 31, 2015, based on the application for reactivation that the contractor received on that date. The propriety of the contractor's action is governed by 42 C.F.R. § 424.520(d). The regulation states that:

> The effective date for billing privileges for physicians, . . . 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.

The effective reactivation date of August 31, 2015, that the contractor assigned to Petitioner was the *earliest possible* effective date that Petitioner could have received inasmuch as the contractor received Petitioner's application for reactivation on that date.

Petitioner makes a series of fact assertions that he contends raise a dispute as to the material facts of this case. I find that they raise no dispute because the assertions are irrelevant.

Petitioner contends that, in 2005, CMS stopped paying his Medicare reimbursement claims. He contends that he demanded an explanation from CMS but that he did not receive one until years later. Petitioner's brief at 2. Whether or not this is true is irrelevant because, at best, it relates to the reasons for the contractor's deactivation of Petitioner's PTAN. As I have explained Petitioner may not challenge that action.[1]

Petitioner then asserts that beginning in September 2013 he engaged in a "lengthy campaign of letter-writing, phone calls, and emails to CMS to

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[1] Petitioner has not explained how the alleged refusal to pay his claims beginning in 2005 has anything to do with deactivation of his PTAN in 2008.

get a clear answer about why he had not been reimbursed after eight years of providing payments [*sic*] to Medicare beneficiaries, submitting claims to Medicare, and not being paid." Petitioner's brief at 3. This assertion plainly is irrelevant because it relates to deactivation of Petitioner's PTAN.

Next, Petitioner asserts that in September 2015 someone named "Mary F" explained to him that he was "dropped from the reimbursement system" when CMS transitioned from paper claims to a new on-line reimbursement system (PECOS). Petitioner's brief at 3. Petitioner has not explained how this assertion – assuming it to be correct – relates to the contractor's deactivation of Petitioner's PTAN in 2012. But, even if there is some relationship, the attributed statement by "Mary F" is irrelevant for the reasons that I have explained. Petitioner may not challenge the contractor's deactivation of his PTAN.

Taken as a whole, Petitioner's arguments seem to add up to a contention that the contractor treated him unfairly, and that as a matter of equity, he should be entitled to claim reimbursement for services that he provided earlier than August 31, 2015. If that is Petitioner's argument I have no authority to hear it. My authority is limited in this case to deciding whether CMS or its contractor acted appropriately consistent with regulatory authority. *US Ultrasound,* DAB No. 2302, at 8 (2010).

Finally, Petitioner seems to be making an argument that the contractor did not give him adequate notice in 2012 for the reasons for deactivating his PTAN. That assertion again is a challenge to the deactivation of his PTAN. As I have explained, I have no authority to hear that challenge, whether direct or indirect. If I cannot consider the propriety of a deactivation then the issue of notice is also something that I have no authority to consider, inasmuch as Petitioner has no right to challenge the substantive grounds for deactivation.

s/Steven K. Kessel

Steven K. Kessel

APPENDIX G

42 U.S.C.A. § 405
Evidence, procedure, and certification for payments [Statutory Text & Notes of Decisions subdivisions I to VIII]

Effective: December 27, 2020

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(g) Judicial review

Any individual, after any final decision of the Commissioner of Social Security made after a hearing to which he was a party, irrespective of the amount in controversy, may obtain a review of such decision by a civil action commenced within sixty days after the mailing to him of notice of such decision or within such further time as the Commissioner of Social Security may allow. Such action shall be brought in the district court of the United States for the judicial district in which the plaintiff resides, or has his principal place of business, or, if he does not reside or have his principal place of business within any such judicial district, in the United States District Court for the District of Columbia. As part of the Commissioner's answer the Commissioner of Social Security shall file a certified copy of the transcript of the record including the evidence upon which the findings and decision complained of are based. The court shall

have power to enter, upon the pleadings and transcript of the record, a judgment affirming, modifying, or reversing the decision of the Commissioner of Social Security, with or without remanding the cause for a rehearing. The findings of the Commissioner of Social Security as to any fact, if supported by substantial evidence, shall be conclusive, and where a claim has been denied by the Commissioner of Social Security or a decision is rendered under subsection (b) of this section which is adverse to an individual who was a party to the hearing before the Commissioner of Social Security, because of failure of the claimant or such individual to submit proof in conformity with any regulation prescribed under subsection (a) of this section, the court shall review only the question of conformity with such regulations and the validity of such regulations. The court may, on motion of the Commissioner of Social Security made for good cause shown before the Commissioner files the Commissioner's answer, remand the case to the Commissioner of Social Security for further action by the Commissioner of Social Security, and it may at any time order additional evidence to be taken before the Commissioner of Social Security, but only upon a showing that there is new evidence which is material and that there is good cause for the failure to incorporate such evidence into the record in a prior proceeding; and the Commissioner of Social Security shall, after the case is remanded, and after hearing such additional evidence if so ordered, modify or affirm the Commissioner's findings of fact or the Commissioner's decision, or both, and shall file with the court any such additional and modified findings

of fact and decision, and, in any case in which the Commissioner has not made a decision fully favorable to the individual, a transcript of the additional record and testimony upon which the Commissioner's action in modifying or affirming was based. Such additional or modified findings of fact and decision shall be reviewable only to the extent provided for review of the original findings of fact and decision. The judgment of the court shall be final except that it shall be subject to review in the same manner as a judgment in other civil actions. Any action instituted in accordance with this subsection shall survive notwithstanding any change in the person occupying the office of Commissioner of Social Security or any vacancy in such office.

APPENDIX H

42 U.S.C.A. § 1395cc
Agreements with providers of services; enrollment processes

Effective: December 27, 2020

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(h) Dissatisfaction with determination of Secretary; appeal by institutions or agencies; single notice and hearing.

(1)(A) Except as provided in paragraph (2), an institution or agency dissatisfied with a determination by the Secretary that it is not a provider of services or with a determination described in subsection (b)(2) shall be entitled to a hearing thereon by the Secretary (after reasonable notice) to the same extent as is provided in section 405(b) of this title, and to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) of this title, except that, in so applying such sections and in applying section 405(l) of this title thereto, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

. . .

(8) Hearing rights in cases of denial or non-renewal.

A provider of services or supplier whose application to enroll (or, if applicable, to renew enrollment) under this subchapter is denied may have a hearing and judicial review of such denial under the procedures that apply under subsection (h)(1)(A) to a provider of services that is dissatisfied with a determination by the Secretary.

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APPENDIX I

Title 42 – Public Health

Chapter IV CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

Subchapter B – MEDICARE PROGRAM

Part 424 – CONDITIONS FOR MEDICARE PAYMENT

Subpart P – Requirements for Establishing and Maintaining Medicare Billing Privileges

§ 424.520 Effective date of Medicare billing privileges.

Effective: January 1, 2021

(a) *Surveyed, certified or accredited providers and suppliers.* The effective date for billing privileges for providers and suppliers requiring State survey, certification or accreditation is specified in § 489.13 of this chapter. If a provider or supplier is seeking accreditation from a CMS–approved accreditation organization, the effective date is specified in § 489.13.

(b) *Independent Diagnostic Testing Facilities.* The effective date for billing privileges for IDTFs is specified in § 410.33(i) of this chapter.

(c) *DMEPOS suppliers.* The effective date for billing privileges for DMEPOS suppliers is specified in § 424.57(b) of this subpart and section 1834(j)(1)(A) of the Act.

(d) *Physicians, non-physician practitioners, physician and non-physician practitioner organizations, ambulance suppliers, opioid treatment programs, and home infusion therapy suppliers.* The effective date for billing privileges for physicians, non-physician practitioners, physician and non-physician practitioner organizations, ambulance suppliers, opioid treatment programs, and home infusion therapy suppliers is the later of—

(1) The date of filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor; or

(2) The date that the supplier first began furnishing services at a new practice location.

APPENDIX J

Title 42 - Public Health

Chapter IV - CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

Subchapter B -

MEDICARE PROGRAM

(CONTINUED) Part 424 -

CONDITIONS FOR

MEDICARE PAYMENT

Subpart P - Requirements for Establishing and Maintaining Medicare Billing Privileges

Effective: November 4, 2019

§ 424.540 - Deactivation of Medicare billing privileges.

(a) *Reasons for deactivation.* CMS may deactivate the Medicare billing privileges of a provider or supplier for any of the following reasons:

(1) The provider or supplier does not submit any Medicare claims for 12 consecutive calendar

months. The 12 month period will begin the 1st day of the 1st month without a claims submission through the last day of the 12th month without a submitted claim.

(2) 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. Changes that must be reported include, but are not limited to, a change in practice location, a change of any managing employee, and a change in billing services. A change in ownership or control must be reported within 30 calendar days as specified in § 424.520(b) and § 424.550(b)

(3) The provider or supplier does not furnish complete and accurate information and all supporting documentation within 90 calendar days of receipt of notification from CMS to submit an enrollment application and supporting documentation, or resubmit and certify to the accuracy of its enrollment information.

(b) *Reactivation of billing privileges.*

(1) In order for a deactivated provider or supplier to reactivate its Medicare billing privileges, the provider or supplier must recertify that its enrollment information currently on file with Medicare is correct and furnish any missing information as appropriate.

(2) Notwithstanding paragraph (b)(1) of this section, CMS may, for any reason, require a deactivated provider or supplier to, as a prerequisite for reactivating its billing privileges, submit a complete Form CMS–855 application.

(3) Except as provided in paragraph (b)(3)(i) of this section, reactivation of Medicare billing privileges does not require a new certification of the provider or supplier by the State survey agency or the establishment of a new provider agreement.

(i) An HHA whose Medicare billing privileges are deactivated under the provisions found at paragraph (a) of this section must obtain an initial State survey or accreditation by an approved accreditation organization before its Medicare billing privileges can be reactivated.

(ii) [Reserved]

(c) *Effect of deactivation.* Deactivation of Medicare billing privileges is considered an action to protect the provider or supplier from misuse of its billing number and to protect the Medicare Trust Funds from unnecessary overpayments. The deactivation of Medicare billing privileges does not have any effect on a provider or supplier's participation agreement or any conditions of participation.

APPENDIX K

Title 42 – Public Health

Chapter IV CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

Subchapter B – MEDICARE PROGRAM

Part 424 – CONDITIONS FOR MEDICARE PAYMENT

Subpart P – Requirements for Establishing and Maintaining Medicare Billing Privileges

42 C.F.R. § 424.555
Payment liability.
Effective: June 20, 2006

(a) No payment may be made for otherwise Medicare covered items or services furnished to a Medicare beneficiary by suppliers of durable medical equipment, prosthetics, orthotics, and other supplies unless the supplier obtains (and renews, as set forth in section 1834(j) of the Act) Medicare billing privileges.

(b) No 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,

denied, or revoked. The Medicare beneficiary has no financial responsibility for expenses, and the provider or supplier must refund on a timely basis to the Medicare beneficiary any amounts collected from the Medicare beneficiary for these otherwise Medicare covered items or services.

(c) If any provider or supplier furnishes an otherwise Medicare covered item or service for which payment may not be made by reason of paragraph (b) of this section, any expense incurred for such otherwise Medicare covered item or service shall be the responsibility of the provider or supplier. The provider or supplier may also be criminally liable for pursuing payments that may not be made by reason of paragraph (b) of this section, in accordance with section 1128B(a)(3) of the Act.