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4	UNITED STATES	DISTRICT COURT
5	NORTHERN DISTR	ICT OF CALIFORNIA
6	SAN JOSE DIVISION	
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8	EDGAR A. GAMBOA, M.D., MEDICAL CORP.,	Case No. <u>5:22-cv-02865-EJD</u>
9	Plaintiff,	ORDER ON CROSS MOTIONS FOR SUMMARY JUDGMENT
10	v.	Re: ECF Nos. 22, 25
11	XAVIER BECERRA,	Re. ECT 1108. 22, 25
12	Defendant.	
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14	Plaintiff Dr. Edgar Gamboa seeks judicial review of the Medicare Appeals Council	
15	("Council") decision finding that he had improperly billed ClariVein procedures and that he was	
16	not "without fault" for the overpayments. Defen	dant Health and Human Services Secretary
17	Xavier Becerra has filed excerpts of the administ	trative record. ECF No. 18 ("A.R."). Both parties
18	have moved for summary judgment in their favo	r. ECF Nos. 22 ("Pl. MSJ"), 25 ("Opp.").
19	Based on the following, the Court GRAN	TTS IN PART and DENIES IN PART the parties'
20	cross motions. The Council's decision is AFFIR	MED IN PART, VACATED IN PART, and shall
21	be REMANDED for further administrative proce	eedings.
22	I. BACKGROUND	
23	A. Medicare and Health Care Prov	viders
24	Medicare is a federal health insurance pro	ogram that covers aged and disabled individuals.
25	See 42 U.S.C. § 1395, et seq. The Centers for M	edicare and Medicaid Services ("CMS") is the
26	federal agency that administers the program on b	wehalf of the Defendant Secretary of Health and
27	Human Services. 42 U.S.C. § 1395hh(a)(1). Th	is case involves Part B of the Medicare program,
28	Case No.: <u>5:22-cv-02865-EJD</u> ORDER ON CROSS MOTIONS FOR SUMMA	RY JUDGMENT
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which authorizes payments to health care providers for outpatient care, services, and durable medical equipment. *Id.* §§ 1395j, 1395k.

Medicare service providers like Dr. Gamboa submit claims for reimbursement of covered services they provided, and Medicare Administrative Contractors ("MACs") make initial determinations as to the claims' coverage and amounts. *Id.* § 1395ff(a); 42 C.F.R. § 405.920. MACs generally will reimburse claims immediately unless they contain glaring irregularities, and a Zone Program Integrity Contractor ("ZPIC") may subsequently audit the payments to determine overpayment or underpayment. 42 U.S.C. § 1395ddd(h). If there is an overpayment, the MAC can make an adjustment and seek reimbursement from the health care provider. *Id.* § 1395gg.

When health care providers submit claims for reimbursement, they must provide a numeric code for the service or procedure as listed in the Current Procedural Terminology ("CPT"), a coding system maintained by the American Medical Association to identify and describe medical services and procedures. Based on the code provided, CMS will then pay for the covered services pursuant to the Medicare Physician Fee Schedule, which is updated annually based on the relative value units of that service or procedure. Pl. MSJ 6 n.2; Opp. 3–4. "To promote consistency in initial determinations," MACs can issue a local coverage determination ("LCD"), which "specifies whether or under what conditions that contractor will approve reimbursement for some set of items or services." *Agendia, Inc. v. Becerra*, 4 F.4th 896, 897 (9th Cir. 2021), *cert. denied*, 211 L. Ed. 2d 605 (Jan. 24, 2022); *see also* 42 U.S.C. § 1395kk01(a)(1). MACs can also issue local coverage articles ("LCAs") that address specific coverage and billing issues. Opp. 6.

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B. ClariVein and Noridian's Local Coverage Publications

ClariVein is a relatively new device and procedure for treating varicose veins. Compl. ¶ 23. The procedure involves a physician inserting a catheter into the affected vein that both abrades the vein's interior lining and delivers a medical solution to coat the inside of the vein. *Id.* ¶ 21. ClariVein is purportedly cheaper, faster, and safer than the traditional treatment for varicose veins, which involves vein stripping and ligation under anesthesia in a hospital. *Id.* ¶ 22.

27 28 Although there was not a specific CPT code for ClariVein during the relevant time period, Case No.: <u>5:22-cv-02865-EJD</u> ORDER ON CROSS MOTIONS FOR SUMMARY JUDGMENT

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United States District Court Northern District of California

1	the most relevant existing CPT codes at the time were: (1) <u>36299</u> for "unlisted procedure, vascular	
2	injection"; (2) <u>37241</u> for "vascular embolization or occlusion," A.R. 11; and (3) <u>37799</u> for	
3	"unlisted procedure, vascular surgery," A.R. 3649.	
4	During the relevant time period, the MAC in this case—Noridian Healthcare Solutions,	
5	LLC ("Noridian")—had not issued any LCD that directly addressed which CPT code physicians	
6	should use for the ClariVein procedure. Pl.' Separate Statement and Responsive Separate	
7	Statement Supp. Reply ("Separate Statement"), Fact 17 (undisputed), ECF No. 26-1, at 9.	
8	However, Noridian had issued some LCAs that did specifically reference ClariVein, as well as an	
9	LCD that provided general guidance on treating varicose veins, as follows:	
10	• <u>LCD L33497</u> , "Treatment of Varicose Veins of the Lower Extremities," provided a list	
11	of codes "typically used to report" treatment of varicose veins. A.R. 3648-49. This	
12	list included CPT code 37799 for "vascular surgery" but did not include either 36299	
13	or 37241. This LCD was effective from Sept. 16, 2013 through Sept. 30, 2015, before	
14	being replaced by L34209. A.R. 3682-83, 3731.	
15	• <u>LCA A53145</u> , ¹ "Sclerosing of Varicose Veins," provided that "CPT 37241 must not be	
16	used to bill for the treatment of varicose veins with [ClariVein]" and "[w]hen using the	
17	ClariVein device in the treatment of varicose veins[,] Noridian recommends billing	
18	with CPT code 36299." See Opp. 6 n.7 (emphasis added) (citing Medicare Coverage	
19	Database Archive, A53145, available at	
20	https://localcoverage.cms.gov/mcd_archive/view/article.aspx?articleInfo=53145:4&ke	
21	yword=A53145). This LCA was revised on April 11, 2014, specifically to "include	
22	billing instructions for the use of ClariVein." Id.	
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24	¹ Although Dr. Gamboa objects that "[n]o copy of LCA A53145 exists in the record" and claims that there is no way to verify the language on any particular date (Separate Statement, Facts 39, 40), the Court takes judicial notice of the past versions of LCA A53145 available at the Medicare Coverage Database Archive, maintained by CMS. <i>See United States v. Kindred Healthcare, Inc.</i> ,	
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26	469 F. Supp. 3d 431, 439 (E.D. Pa. 2020) ("Judicial notice of these documents is proper as the Court may take judicial notice of public records such as those issued by CMS."); U.S. ex rel.	
27	 Modglin v. DJO Glob. Inc., 48 F. Supp. 3d 1362, 1382 (C.D. Cal. 2014) (taking "judicial notice of the documents relators proffer from the websites of the CMS."). Case No.: <u>5:22-cv-02865-EJD</u> ORDER ON CROSS MOTIONS FOR SUMMARY JUDGMENT 	
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- <u>LCA A53084</u>, "Sclerosing of Varicose Veins," provided substantively identical guidance as contained in LCA A53145. *See* A.R. 3748 (emphasis added). This LCA was effective from Oct. 1, 2015 through most of the relevant time period.
- <u>LCD L34209</u>, "Treatment of Varicose Veins of the Lower Extremities," provided that code "**36299** is used for sclerotherapy with mechanical agitation (e.g. Clarivein device) prior to January 1, 2017." A.R. 3734 (emphasis added). This revision was first effective for services performed after Jan. 1, 2017. A.R. 3731.

C. Dr. Gamboa and ClariVein

Plaintiff Dr. Edgar Gamboa was practicing as a general surgeon in the greater Watsonville area from May 2011 until he ceased operations in 2018. Compl. ¶¶ 17, 64. From 2013 through 2018, he was the only general surgeon servicing the region. *Id.* ¶ 17. The majority of Dr. Gamboa's patients were referred to him from county and federal clinics, 80% of whom were insured by either Medi-Cal or Medicare. *Id.* ¶ 18.

In early 2014, Dr. Gamboa began treating patients with varicose veins using a new device and procedure called ClariVein. *Id.* ¶ 23. Between 2014 to November 2016, Dr. Gamboa performed over 90 ClariVein procedures. *Id.* ¶¶ 28, 33. Dr. Gamboa alleges that each ClariVein device cost approximately \$890, and each procedure required the assistance of a certified vascular ultrasound technician ranging from \$150–\$250 per procedure. Decl. Edgar A. Gamboa Supp. Request Reconsideration ("Gamboa Decl.") ¶ 24, ECF No. 18-16.

At first, Dr. Gamboa billed his ClariVein services using the CPT code 37241 for "vascular embolization or occlusion," based on guidance from a ClariVein representative and the AMA's CPT Assistant tool. Separate Statement, Fact 36 (undisputed); *see also* Gamboa Decl. ¶¶ 21, 23; Decision 7, ECF No. 1-1. These claims were submitted to Noridian, the MAC in this case. Compl. ¶ 26. Dr. Gamboa was reimbursed approximately \$4,000 per procedure under CPT code 37241. Gamboa Decl. ¶ 24.

 In June 2016, Dr. Gamboa was informed by a ClariVein representative that Noridian did
 not want ClariVein procedures to be billed with code 37241 and that they should be billed using
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code 36299 instead for "unlisted procedure, vascular injection." Compl. ¶ 29; Separate Statement,
Fact 18 (undisputed). Because code 36299 was an unlisted code, the reimbursement rate is not set
but rather would be separately calculated by Noridian using a variety of factors. Separate
Statement, Fact 18. From June to September 2016, Dr. Gamboa billed eight ClariVein procedures
using CPT code 36299 and was reimbursed at an equivalent rate to code 37241. *Id.*, Fact 3;
Gamboa Decl. ¶ 25.

In November 2016, a Zone Program Integrity Contractor notified Dr. Gamboa that he had incorrectly billed ClariVein procedures using CPT Code 37241, because the procedures "do not reflect vascular embolization or occlusion as defined and valued by" the AMA. Opp. 7. The ZPIC's adjusted CPT Code 36471 for "injection of sclerosing solution; multiple veins, same leg," would reimburse Dr. Gamboa at about \$140 instead of \$4,000 per procedure. *See* Gamboa MSJ 7. Consequently, between December 2016 and January 2017, Noridian adjusted Dr. Gamboa's previously billed ClariVein procedures and concluded that he had been overpaid by approximately \$376,000. Compl. ¶ 36.

D. Administrative and Procedural History

After Noridian's adjustments, Dr. Gamboa proceeded through the four stages of the Medicare administrative appeals process.

18 First, he requested a redetermination from Noridian, which was largely unfavorable. See 19 Edgar A. Gamboa, M.D., Medicare Appeals Council ("Decision"), Dkt. No. M-22-825 (Mar. 11, 2022), ECF No. 1-1, at 7. On the second level of appeal, a Qualified Independent Contractor 20 ("QIC") issued a decision that was partially favorable to Dr. Gamboa, finding that Noridian's 21 "downcoding" was improper and recoding the ClariVein procedures to CPT code 37799 for 22 23 unlisted vascular surgeries. Decision 3. At the third level, an administrative law judge ("ALJ") 24 held a hearing and issued a favorable decision to Dr. Gamboa. Specifically, the ALJ found that 25 Dr. Gamboa had correctly billed the ClariVein procedures under CPT code 37241 because the published LCAs and LCDs during the relevant period were inconsistent amongst themselves. Id. 26 Furthermore, the ALJ found that Dr. Gamboa was indeed "without fault." Id. at 4. 27 Case No.: <u>5:22-cv-</u>02865-EJD 28 ORDER ON CROSS MOTIONS FOR SUMMARY JUDGMENT

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At the fourth and final level of administrative appeal, on March 11, 2022, the Medicare Appeals Council issued a decision that was widely unfavorable to Dr. Gamboa. Specifically, the Council reversed the ALJ's decision and found that the preponderance of the evidence supported a finding that ClariVein services should have been reported as CPT code 36299, not 37241 as Dr. Gamboa had reported. Decision 10. The Council further found that Dr. Gamboa "did not have a reasonable basis for assuming that the initial payments from [Noridian] were correct and was thus not without fault in causing any overpayments," concluding that Dr. Gamboa remained financially responsible for "non-covered costs." Id. at 9-11.

On May 13, 2022, Dr. Gamboa filed the instant Complaint for Judicial Review of Administrative Agency Action. ECF No. 1. On October 12, 2022, Defendant Secretary Becerra filed the administrative record in nine volumes. ECF No. 18. Dr. Gamboa moved for summary judgment on December 19, 2022 (ECF No. 22, "Pl. MSJ"), and Secretary Becerra filed a cross motion for summary judgment and opposition to Dr. Gamboa's motion on February 2, 2023 (ECF No. 25, "Opp.").

II. LEGAL STANDARD

The scope of judicial review over Medicare disputes is determined by two statutes: the Administrative Procedure Act ("APA") and the Social Security Act. See Int'l Rehab. Scis. Inc. v. 18 Sebelius, 688 F.3d 994, 1000 (9th Cir. 2012) (citing 5 U.S.C. § 706); Odell v. U.S. Dep't of Health 19 & Hum. Servs., 995 F.3d 718, 722 (9th Cir. 2021) ("The judicial-review provision in the Medicare 20statute incorporates that of the Social Security Act.").

Under the APA, the Court must uphold a final agency determination unless it is "arbitrary, 21 capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706; see 22 23 also Int'l Rehab., 688 F.3d at 1000.

24 Under the Social Security Act, the Court must affirm the "findings of the Secretary if they 25 are supported by 'substantial evidence' and if the proper legal standard was applied." KGV Easy Leasing Corp. v. Leavitt, 413 F. App'x 966, 967 (9th Cir. 2011) (quoting Mayes v. Massanari, 276 26 F.3d 453, 458–59 (9th Cir. 2001). "The Secretary's factual findings are conclusive if they are 27 Case No.: 5:22-cv-02865-EJD 28 ORDER ON CROSS MOTIONS FOR SUMMARY JUDGMENT

supported by 'substantial evidence.'" *Int'l Rehab.*, 688 F.3d at 1000; 42 U.S.C. § 405(g).
"Substantial evidence' means 'more than a mere scintilla but less than a preponderance; it is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Int'l Rehab.*, 688 F.3d at 1000 (quoting *Sandgathe v. Chater*, 108 F.3d 978, 980 (9th Cir. 1997)).

III. DISCUSSION

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Dr. Gamboa seeks reversal of the Medicare Appeals Council Decision and a judgment consistent with the ALJ's determination in his favor. Compl. at 23; Pl. MSJ 25. In doing so, Dr. Gamboa challenges five aspects of the Decision: (1) the finding that he was overpaid; (2) the finding that he was not "without fault"; (3) the denial of his request to submit further briefing on reconsideration; (4) the Decision's failure to "functionally resolve[]" the dispute; and (5) the violation of his Fifth Amendment procedural and substantive due process rights. Because the Court will remand this matter for further administrative proceedings regarding Dr. Gamboa's fault for overpayment, the Court will not address the third, fourth, and fifth arguments asserted.

A. Council's Finding of Improper Coding

Dr. Gamboa first challenges the Council's determination that "the preponderance of the evidence supports a finding that CPT code 37241 was not the correct code for reporting ClariVein services; the correct code for reporting ClariVein services was CPT code 36299." Decision 8. Specifically, Dr. Gamboa contends that (1) the Decision failed to ascertain the correct amount before finding that he had been overpaid; and (2) he could not have been overpaid because he was paid approximately the same amount under both CPT codes 37241 and 36299. Pl. MSJ 17–18.

21 The Court does not find Dr. Gamboa's arguments to be relevant to the issues on review. The point Dr. Gamboa attempts to argue (*i.e.*, whether he was overpaid) is distinct and wholly 22 23 separate from the limited question before the Council (i.e., whether Dr. Gamboa had incorrectly 24 billed his ClariVein services). Dr. Gamboa attempts to bridge this gap by citing a 1947 Supreme 25 Court case for the definition of "overpayment," Pl. MSJ 17; however, neither this authority nor any other he cites suggest that the quantum of overpayment is relevant to determining whether a 26 provider had billed under an erroneous CPT code. Moreover, Dr. Gamboa had already attempted 27 Case No.: <u>5:22-cv-028</u>65-EJD 28 ORDER ON CROSS MOTIONS FOR SUMMARY JUDGMENT

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once before the Council to reframe the issues from one of erroneous billing to overpayment, which the Council expressly rejected. Decision 5, 8 ("We reiterate that the issue is whether CPT code 37241 was the correct code to use when billing ClariVein procedures."). The Court agrees with the Council's finding on this point and finds it to be supported by substantial evidence, namely the ALJ's express remark in its decision that "[a]t issue is whether procedure code 37241 is an acceptable CPT code for payment of these claims." A.R. 142. In sum, Dr. Gamboa's asserted arguments do not impact the Decision's findings and conclusions regarding the correct CPT code to bill for ClariVein procedures.

Notwithstanding Dr. Gamboa's arguments, the Court finds that the Council's factual findings on this issue are supported by substantial evidence. The Decision relied on two coverage articles Noridian had issued—LCAs A53145 and A53084—where it specifically instructed "[w]hen using the ClariVein device in the treatment of varicose veins[,] Noridian recommends billing with CPT code 36299." Decision 6; *see also* Opp. 6 n.7 (emphasis added). Regardless of the amount of legal deference these articles are entitled to, they reflect enough evidence that "a reasonable mind might accept as adequate to support [the Council's] conclusion," on the correct CPT code for ClariVein. *Int'l Rehab.*, 688 F.3d at 1000. The Court may not probe further into the Council's factual findings once it has confirmed the presence of substantial evidence.

Accordingly, the Court will DENY Dr. Gamboa's motion for summary judgment to reverse the Council's findings on this point.

B. Council's Determination that Plaintiff Was Not "Without Fault"

In addition to challenging the Council's CPT code determination, Dr. Gamboa also takes issue with the Council's determination that he was not "without fault" and, therefore, financially liable for the overpayment between CPT codes 37241 and 36299. Pl. MSJ 18–23.

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1. Availability of § 1395gg(c) Waiver to Providers

Dr. Gamboa invokes the exception at 42 U.S.C. § 1395gg(c), which purportedly allows the government to waive its right to overpayment recovery where the service provider was "without fault" for the overpayment. Pl. MSJ 18 (citing *Action All. of Senior Citizens v. Leavitt*, 483 F.3d Case No.: <u>5:22-cv-02865-EJD</u> ORDER ON CROSS MOTIONS FOR SUMMARY JUDGMENT

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852, 860 (D.C. Cir. 2007) ("[B]y its plain terms, 1395gg applies to overpayments to a 'provider of services' for 'items or services furnished an individual."")). Defendant notes, however, that the Fourth and Seventh Circuits have interpreted the § 1395gg(c) waiver to only be available to individual beneficiaries, *i.e.*, unavailable to Medicare providers. Opp. 16 n.11; see MacKenzie Med. Supply, Inc. v. Leavitt, 506 F.3d 341, 349 (4th Cir. 2007) (holding "§ 1395gg(c) explicitly applies only to the waiver of 'adjustment[s] as provided in subsection (b) of this section,' and the 6 only adjustment contemplated by § 1395gg(b) is an adjustment of payments to individuals not suppliers or providers") (internal citation omitted); Visiting Nurses Ass'n of Sw. Indiana, Inc. v. Shalala, 213 F.3d 352, 359 (7th Cir. 2000) (holding that "the regulations confirm that waiver of overpayment liability for providers is not contemplated by \S 1395gg(c)"). 10

For the purpose of the present review, the Court will not address the continuing viability of § 1395gg(c) to providers. The subject of the Court's review—*i.e*, the Council's Decision—does not rest any of its reasoning on such an argument, and the Court may not affirm the Decision on post hoc arguments that were not raised below. See, e.g., LivinRite, Inc. v. Azar, 386 F. Supp. 3d 644, 667 n.18 (E.D. Va. 2019). The Court, however, will note that the Ninth Circuit has not directly opined on this particular interpretative question, but it has resolved § 1395gg(c) waivers against providers on substantive grounds without considering whether providers were entitled to them in the first place. See, e.g., Garcia v. U.S. Sec'y of Health & Hum. Servs., 542 F. App'x 648 (9th Cir. 2013); Gary Gibbon, M.D., Inc. v. Thompson, 121 F. App'x 703, 705 (9th Cir. 2005). In short, the Court will accept without deciding the Council's and parties' premise that Dr. Gamboa may be eligible for the "without fault" waiver provided by § 1395gg(c).

2. Analysis

23 Assuming the applicability of § 1395gg(c) to Medicare providers, both Dr. Gamboa and 24 Defendant Secretary appear to agree that the Medicare Financial Management Manual (the 25 "Manual"), Ch. 3, § 90 provides the relevant agency guidance for evaluating whether a provider is "without fault." See Pl. MSJ 19; Opp. 16–17 (citing Manual, Ch. 3, § 90). The Manual states that 26 a provider is without fault for an overpayment "if it exercised reasonable care in billing for, and 27 Case No.: <u>5:22-cv-</u>02865-EJD 28 ORDER ON CROSS MOTIONS FOR SUMMARY JUDGMENT

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accepting, the payment" and "[o]n the basis of the information available to it . . . it had a reasonable basis for assuming that the payment was correct." Manual, Ch. 3, § 90. The Manual also lists several situations where providers are liable for overpayments, one of which is when the provider billed or Medicare paid for "Services that the Provider . . . Should Have Known Were Noncovered." Manual, Ch. 3, § 90.1(H).²

In reversing the ALJ's determination that Dr. Gamboa was "without fault" as to the overpayment, the Council cited three facts: (1) Dr. Gamboa had access to coverage authorities that indicated CPT code 36299 was the proper code for ClariVein; (2) Dr. Gamboa had the burden to show that no overpayment occurred per § 1833(e) of the Social Security Act; and (3) although Dr. Gamboa alleged he was reimbursed at equivalent rates under both CPT codes 36299 and 37241, he did not provide payment records to substantiate that statement. Decision 9. Based on the Decision's reasoning, the Court finds both that the Council failed to properly apply the Manual's standards and that its factual finding of fault is not supported by substantial evidence.

<u>First</u>, although the Council was correct to decline Dr. Gamboa's invitation to consider overpayment in reviewing the ALJ's decision on the correct CPT code for ClariVein, it was error to ignore the quantum of payment in assessing Dr. Gamboa's fault. The Manual's guidance on evaluating providers' fault in overpayments repeatedly emphasizes the salience of the payment's reasonableness. *See* Manual, Ch. 3, § 90 (stating a provider is "without fault, if it exercised *reasonable care in billing for*, and accepting, *the payment*"; "had a reasonable basis for *assuming that the payment was correct*"; and "if it had *reason to question the payment*; it promptly brought the question to the contractor's attention"). These instructions clarify that, although the provider's reasonable care in billing is relevant, the primary subject of the reasonableness inquiry is the *payment* the provider received. Similarly, to the extent the Council's finding of fault turned on Dr.

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² Per CMS' website, the Manual contains "CMS' program issuances, day-to-day operating instructions, policies, and procedures that are based on statutes, regulations, guidelines, models, and directives. The CMS program components, providers, contractors, Medicare Advantage

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and directives. The CMS program components, providers, contractors, Medicare Advantage organizations and state survey agencies use the IOMs to administer CMS programs." *Internet-Only Manuals (IOMs)*, Centers for Medicare & Medicaid Services,

https://www.cms.gov/medicare/regulations-guidance/manuals/internet-only-manuals-ioms. Case No.: <u>5:22-cv-02865-EJD</u>

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Gamboa's § 1833(e) obligations to furnish information in the first instance when he submitted claims for reimbursement (Decision 9), those obligations are relevant but cannot be determinative of a fault finding without considering the payments received. Here, the Council failed to make *any* affirmative findings as to the reasonableness or unreasonableness of the payments Dr.
Gamboa received for ClariVein procedures billed under CPT Code 37241, which was error under the Manual's guidance.

<u>Second</u>, the Court also finds that the Council's finding of fault is unsupported by substantial evidence. As noted above, the Decision is generally bereft evidence or factual findings as to the reasonableness of the payments that Dr. Gamboa received. The only pertinent evidence cited by the Decision is Dr. Gamboa's access to the LCAs that suggested CPT code 37241 should not be used for ClariVein. Decision 9. However, the Council itself recognized that the applicable LCDs—which are typically entitled to the most substantial deference—"did not directly address the ClariVein procedure or CPT Code 37241." Opinion 6. As a result, the Council was required to rely on LCAs, which it acknowledged "are not entitled to substantial deference." *Id.* Although the LCAs are indeed relevant evidence, the Court cannot determine that they present "more than a mere scintilla" or "such relevant evidence as a reasonable mind might accept as adequate to support" a finding of fault as required by the Manual. *Int'l Rehab.*, 688 F.3d at 1000. Because the only evidence cited is a publication not entitled to deference that only speaks to the reasonableness of Dr. Gamboa's *billing* practices but not the reasonableness of payments received, the Court finds this evidence insufficient to support the Council's factual finding of fault.

Both the Council and Defendant rely on § 90.1.H of the Manual for support, which states that providers are at fault if they were paid for services that the providers should have known were not covered by Medicare. Decision 9; Opp. 16 n.12. Here, however, there is no dispute that ClariVein procedures were covered by Medicare, nor is there any dispute that the procedures were medically necessary. Separate Statement, Fact 23 (undisputed). Consequently, Section 90.1.H which expressly addresses only situations where the provider was paid for services that he should have known were not covered—does not fully control in situations where the services were

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indisputably covered and only the amount of reimbursement is disputed. Moreover, Section 90.1.H also contains a caveat that, in addition to a provider's subjective ignorance of coverage provisions, "there may be other circumstances that justify a finding that the provider, physician, or other supplier was not at fault," such as "whether and to what extent a coverage rule is spelled out in regulations, instructions, or in a CMS notice." Manual, Ch. 3, § 90.1.H. Here, although the Council cited the fact that Dr. Gamboa had "access to the coverage authorities and coding guidance," it did not appear to have considered "whether and to what extent a coverage rule is spelled out in regulations, instructions, or in a CMS notice."³ *See* Decision 9. Accordingly, the Court concludes that Defendant's reliance on the exemplar set forth in § 90.1.H of the Manual is largely misplaced, as this case does not involve a provider being paid for non-covered services.

Because the Council erroneously applied the standards set forth in the Manual and its 11 12 finding of fault is unsupported by substantial evidence, the Court will not affirm the Council's 13 Decision as requested by the Defendant. Accordingly, the Court may modify or reverse the 14 Council's Decision, with or without remanding for a rehearing. 42 U.S.C. § 405(g); 42 U.S.C. 15 § 1395ff(b)(1)(A). Here, the Court finds that further proceedings are warranted. In addition to the 16 infirmities noted above, the Decision acknowledged that Dr. Gamboa had alleged he was reimbursed at equivalent rates under both CPT code 37241 and 36299, but ultimately rejected this 17 18 allegation because Dr. Gamboa had "provided no payment records to substantiate the provider's 19 declaration" and further denied him the opportunity to submit written briefs.⁴ Decision 9. Dr. 20Gamboa strenuously rebuts this characterization, arguing that he had appended overpayment invoices from CMS that reflect the amounts that CMS had adjusted and, correspondingly, he had 21

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³ Indeed, the Council had flagged the ambiguity surrounding ClariVein coding at the time Dr. Gamboa submitted his claims for reimbursement. *See* Decision 6 (remarking that "[d]uring the dates of service at issue, various applicable versions of LCD L33497 and 34209 did not directly address the ClariVein procedure or CPT Code 37241") (internal parentheticals omitted), 7–8
(noting the mixed ClariVein coding recommendations from *CPT Assistant*). Although the Council found this evidence unpersuasive in its analysis of the proper coding, this evidence appears to carry different weight as to the assessment of Dr. Gamboa's fault for the overpayments.

 ²⁶ carry different weight as to the assessment of Dr. Gamboa's fault for the overpayments.
 ⁴ This, too, appears to run afoul of the Manual's directives, which instructs that "[w]here it is not clear [whether the provider was without fault in causing the overpayment], the contractor *shall develop the issue*." Manual, Ch. 3, § 90 (emphasis added).

 $[\]begin{array}{c} a evelop me issue. Waldal, Ch. 5\\ 28 \\ \hline Case No.: \underline{5:22\text{-}cv\text{-}02865\text{-}EJD} \end{array}$

¹²

1	previously been paid. See Pl. MSJ 20–21 (citing Gamboa Decl., Ex. B, A.R. 4894–95)). It is
2	unclear whether the Council had reviewed or considered this evidence in representing that there
3	was no evidence substantiating Dr. Gamboa's allegations, but the Decision's language suggests
4	that such evidence would be pertinent to and could impact the Council's ultimate decision-
5	making. The Court finds that further factual development as to the amounts Dr. Gamboa had
6	received for his ClariVein services would benefit the administrative record and will therefore
7	REMAND this matter for further administrative proceedings and, if necessary, rehearing.
8	IV. CONCLUSION
9	Based on the foregoing, the Court will GRANT IN PART and DENY IN PART both
10	parties' motions for summary judgment, as follows:
11	1. The Council's Decision is AFFIRMED as to its determinations on the correct CPT
12	code for billing ClariVein procedures;
13	2. The Council's Decision is VACATED as to its finding that Plaintiff was not "without
14	fault" in causing overpayments;
15	3. The matter is REMANDED for further proceedings consistent with this Order on the
16	issue of Plaintiff's fault;
17	4. Plaintiff's remaining arguments are DENIED WITHOUT PREJUDICE.
18	IT IS SO ORDERED.
19	Dated: September 29, 2023
20	Fallyh
21	EDWARD J. DAVILA United States District Judge
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28	Case No.: <u>5:22-cv-02865-EJD</u> ORDER ON CROSS MOTIONS FOR SUMMARY JUDGMENT 13
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United States District Court Northern District of California