UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, **Plaintiff,** **v.** **REGENERON PHARMACEUTICALS, INC.,** **Defendant.**	**Civil Action No. 20-11217-FDS**

MEMORANDUM AND ORDER ON THE GOVERNMENT'S MOTION FOR PARTIAL SUMMARY JUDGMENT AND DEFENDANT'S MOTION TO STRIKE DENNIS SENDROS'S AMENDED DECLARATION

SAYLOR, J.

This is a case alleging violations of the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b, and False Claims Act ("FCA"), 31 U.S.C. §§ 3729 *et seq.*, by a pharmaceutical company. The United States has brought suit against Regeneron Pharmaceuticals, Inc., the manufacturer of a drug named Eylea, alleging that Regeneron improperly funneled millions of dollars to the Chronic Disease Fund ("CDF")—a purportedly independent charitable foundation—to subsidize patient copays for Eylea.

According to the government, the purpose of the payments was to induce physicians to increase prescriptions of the drug at the expense of the Medicare Part B program. Among other things, the government asserts that the contributions to the foundation were not motivated by a charitable purpose; instead, Regeneron employees solicited and received Eylea-specific data from CDF and improperly used that data to determine the specific amounts Regeneron would

contribute, and their purpose in doing so, according to the government, was to increase sales of Eylea. The amended complaint alleges that Regeneron's actions violated the AKS and caused the submission of false claims for payment to Medicare.

For its part, Regeneron contends that it donated to a *bona fide*, independent charity in a manner that complied with the government's regulatory guidance. It further asserts that its donations did not result in or cause any false claims because it was not the only donor for a significant portion of the relevant period; that CDF awarded assistance on a first-come, first-served basis without regard to whether patients used Eylea or another FDA-approved treatment; that CDF had sufficient funds to cover all copay support provided to Eylea patients in 2013 and 2014 without any donations from Regeneron in each respective year; and that a majority of Eylea patients in 2013 were allocated funds from CDF before Regeneron made a single donation.

In 2023, the government moved for partial summary judgment on the issues of materiality, causation, and damages under the 2010 amendment to the AKS. The Court denied that motion. The government has now moved for partial summary judgment on certain issues of falsity, materiality, and causation under the false certification theory of liability. Regeneron has moved to strike the amended declaration of CMS employee Dennis Sendros, an affidavit upon which the government relies to establish certifications of compliance with the AKS and materiality.

For the following reasons, the government's partial motion for summary judgment will be granted in part and denied in part and defendant's motion to strike the amended Sendros declaration will be denied.

I. Background

Unless otherwise noted, the following facts are undisputed.

A. Factual Background

The Court assumes familiarity with the background of this case. *See United States v. Regeneron Pharms., Inc.*, 2023 WL 6296393 (D. Mass. Sept. 27, 2023), *aff'd*, 128 F.4th 324 (1st Cir. 2025).

1. The Parties and the Medicare Copay Assistance Program

Regeneron Pharmaceuticals, Inc. is a pharmaceutical company. (Answer ¶ 10). It manufactures Eylea, a drug that treats neovascular (wet) age-related macular degeneration ("AMD"), an eye disease that primarily affects elderly people. (*Id.* ¶¶ 10, 29). Eylea is administered by injection into the eye at a physician's office. (*Id.* ¶ 29).

Throughout the period from 2012 through 2014, the other primary drugs used by physicians to treat wet AMD were Lucentis and Avastin, both of which are manufactured by Genentech. (Am. Compl. ¶ 30; Def.'s SUF I ¶ 4).

Medicare, including the Part B program, covers physician-administered drugs, including Eylea. (Answer ¶ 13). Eylea is a "buy and bill" drug, which means that physicians buy the drug before prescribing and administering it to patients, filing a claim with Medicare (and, if applicable, a claim with a charity for copay assistance for the patient), and receiving reimbursement. (*See* Docket No. 275, Ex. 2 ("Kiss Dep. Tr.") 328:14-329:3).

2. Regeneron's Donations to CDF

The Chronic Disease Fund ("CDF") is a patient-assistance foundation. (Gov't's SUF I ¶ 6). More than 99% of CDF's funding comes from pharmaceutical manufacturers. (*Id.* ¶ 7; Docket No. 226, Ex. 3 ("Walley Dep. Tr.") 20:5-10).

From at least 2007 through 2014, CDF operated a fund to provide copay assistance to wet AMD patients (the "AMD fund"). (Def.'s SUF I ¶ 15; Docket No. 247, Ex. 18 ("Walley Decl.") ¶ 5). The AMD fund covered copays, deductibles, and co-insurance for Medicare patients who

were prescribed AMD drugs. (Gov't's SUF I ¶ 9; Walley Dep. Tr. 26:5-27:14). Originally, the AMD fund covered three FDA-approved treatments for wet AMD: Lucentis, Macugen, and Visudyne. (Def.'s SUF I ¶ 18; Walley Decl. ¶ 6). It did not, however, cover Avastin, which is used off-label for the treatment of wet AMD. (*See* Def.'s SUF I ¶ 9). In 2011, after Eylea received FDA approval, the AMD fund added it as well. (Def.'s SUF I ¶ 19; Walley Decl. ¶ 6).

Regeneron had no role in establishing the AMD fund. (Def.'s SUF I ¶ 16; Walley Decl. ¶ 5). Before 2011, Genentech, the manufacturer of Lucentis and Avastin, was the only manufacturer-donor to the AMD fund; it remained its leading donor until the end of 2013. (Def.'s SUF I ¶ 29; Walley Decl. ¶ 15). In 2014, Regeneron became the AMD fund's only manufacturer-donor. (Def.'s SUF I ¶ 31; Walley Decl. ¶ 16). Patients who received copay assistance for treatments from the AMD fund were not provided any information from CDF about the source of the assistance they received. (Def.'s SUF I ¶ 28; Walley Decl. ¶ 13).

B. Regulatory Framework

The False Claims Act, 31 U.S.C. §§ 3729-33, provides for civil liability for anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A), (a)(1)(B). A "claim" is "any request or demand . . . for money or property . . . presented to an officer, employee, or agent of the United States." 31 U.S.C. § 3729(b)(2).

The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, states that "[w]hoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person . . . to purchase . . . or recommend purchasing . . . any good, facility, service, or item for which

payment may be made in whole or in part under a Federal health care program" shall be guilty of a felony. 42 U.S.C. § 1320a-7b(b)(2).

There are two pathways by which the government can prove FCA liability in connection with an AKS violation. Under the "false certification" theory of liability, a person violates the FCA when he or she (1) "presents, or causes to be presented" a false claim, or (2) "makes, uses, or causes to be made or used" a false statement material to a false claim, that "misrepresents compliance with a statutory, regulatory, or contractual requirement that [he or she] knows is material to the government's payment decision." 31 U.S.C. § 3729(a)(1)(A); *id.* § 3729(a)(1)(B); *United States v. Regeneron Pharms., Inc.*, 128 F.4th 324, 332 (1st Cir. 2025) (quoting *Universal Health Servs., Inc. v. United States*, 579 U.S. 176, 181 (2016)) (citation modified).

The 2010 Amendment to the AKS did not displace that pathway. *Regeneron*, 128 F.4th at 333-34 (citing *United States ex rel Cairns v. D.S. Med. LLC*, 42 F.4th 828, 836 (8th Cir. 2022). That amendment provides, as an alternative theory of liability, that a person violates the FCA when he or she (1) "presents, or causes to be presented" a false claim, or (2) "makes, uses, or causes to be made or used" a false statement material to a false claim, "that includes items or services resulting from a violation of [the AKS]." 31 U.S.C. § 3729(a)(1)(A); *id.* § 3729(a)(1)(B); *Regeneron*, 128 F.4th at 326 (citing 42 U.S.C. § 1320a-7b) (alterations in original) (emphasis removed). In other words, under the 2010 Amendment, an "AKS violation that results in a federal health care payment is a per se false claim under the FCA." *Guilfoile v. Shields*, 913 F.3d 178, 190 (1st Cir. 2019) (quoting *United States ex rel. Lutz v. United States*, 853 F.3d 131, 135 (4th Cir. 2017)).

C. Procedural Background

As amended, the complaint asserts three counts: presentation of false claims in violation of the FCA, 31 U.S.C. § 3729(a)(1)(A) (2009) (Count 1); making or using false records material to a false or fraudulent claim in violation of the FCA, 31 U.S.C. § 3729(a)(1)(B) (2009) (Count 2); and unjust enrichment (Count 3). Essentially, the complaint alleges that Regeneron's efforts to funnel money into CDF to reimburse the copays of Eylea patients violated the AKS. The resulting claims to Medicare were allegedly tainted by illegal kickbacks in violation of the FCA.

In 2023, the government moved for partial summary judgment on the issues of materiality, causation, and damages under the 2010 amendment theory of liability. Defendant moved for summary judgment on all counts. The Court denied the government's motion, in part, because it held that under the 2010 amendment to the AKS, the government must prove that the underlying AKS violation was a but-for cause of the false claim. In October 2023, the Court certified an interlocutory appeal of that portion of its order that addressed the 2010 amendment's causation standard. On February 18, 2025, the First Circuit affirmed the Court's ruling.

In May 2025, the government moved for leave to file a second motion for partial summary judgment and to reopen discovery on a limited basis—specifically, discovery concerning liability under the false certification theory. The Court granted that motion.

The government has now filed a second motion for partial summary judgment as to certain issues of falsity, materiality, and causation under the false certification theory of liability. Defendant has moved to strike the amended declaration of CMS employee Dennis Sendros, upon which the government relies in support of its motion.

II. Standard of Review

The role of summary judgment is "to pierce the pleadings and to assess the proof in order to see whether there is a genuine need for trial." *Mesnick v. General Elec. Co.*, 950 F.2d 816,

822 (1st Cir. 1991) (quoting *Garside v. Osco Drug, Inc.*, 895 F.2d 46, 50 (1st Cir. 1990)). Summary judgment shall be granted when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A genuine issue is "one that must be decided at trial because the evidence, viewed in the light most flattering to the nonmovant, would permit a rational factfinder to resolve the issue in favor of either party." *Medina-Munoz v. R.J. Reynolds Tobacco Co.*, 896 F.2d 5, 8 (1st Cir. 1990) (citation omitted). In evaluating a summary judgment motion, the court indulges all reasonable inferences in favor of the nonmoving party. *See O'Connor v. Steeves*, 994 F.2d 905, 907 (1st Cir. 1993). When "a properly supported motion for summary judgment is made, the adverse party must set forth specific facts showing that there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986) (quotations omitted). The nonmoving party may not simply "rest upon mere allegation or denials of his pleading," but instead must "present affirmative evidence." *Id.* at 256-57.

III. Analysis

A. Defendant's Motion to Strike

Because the disposition of the motion to strike may affect the evidentiary record, the Court will address it first.

In substance, the amended declaration of Dennis Sendros makes three sets of disputed assertions. First, he asserts that during the period from 2013 to 2014, physicians were required (1) to submit the CMS-855I form to participate in the Medicare program; (2) to submit the CMS-1500 paper form or CMS-837P electronic form to seek reimbursement from Medicare Part B; and (3) if submitting the CMS-837P electronic form, to complete the CMS-10164B form, an electronic data interchange enrollment form ("EDI form"). Second, he asserts that all of those forms included certifications of compliance with the AKS. Third, he asserts that compliance

with the AKS was material to CMS's payment decisions. Defendant has moved to strike the declaration on the ground that Sendros lacks personal knowledge of those subjects.

Under Fed. R. Civ. P. 56(c)(4), "[a]n affidavit or declaration used to support or oppose a motion must be made on personal knowledge, set out facts that would be admissible in evidence, and show that the affiant or declarant is competent to testify on the matters stated." The "requisite personal knowledge must concern facts as opposed to conclusions, assumptions, or surmise." *Livick v. The Gillette Co.*, 524 F.3d 24, 28 (1st Cir. 2008) (internal quotation marks omitted). "On a motion for summary judgment, the district court should disregard only those portions of an affidavit that are inadequate and consider the rest." *Perez v. Volvo Car Corp.*, 247 F.3d 303, 315 (1st Cir. 2001) (quoting *Akin v. Q-L Invs., Inc.*, 959 F.2d 521, 531 (5th Cir. 1992)). In making this inquiry, "personal knowledge is the touchstone." *Id.*

Several of defendant's contentions in support of the motion to strike may be dismissed summarily. To the extent that the Sendros declaration simply recounts basic Medicare requirements and procedures that are set out in published regulations and the contents of publicly available CMS forms, the Court may take judicial notice of those matters. *See Getty Petroleum Mktg., Inc. v. Cap. Terminal Co.*, 391 F.3d 312, 320 (1st Cir. 2004); *Gent v. CUNA Mut. Ins. Soc'y*, 611 F.3d 79, 84 n.5 (1st Cir. 2010) (taking judicial notice of relevant facts on CDC's website, as they were "not subject to reasonable dispute."). And to the extent Sendros is simply authenticating Medicare forms—that is, stating that the forms are what they purport to be—his testimony is admissible under Fed. R. Evid. 901(b)(7)(B) (rendering admissible evidence that "a purported public record or statement is from the office where items of this kind are kept"). A current employee of a government agency can authenticate a record from the files of that agency,

even if the employee does not have personal knowledge of the contents of the record and was not employed at the agency at the time when the record was created.

There are, however, some gaps in Sendros's descriptions of the relevant medical forms, which appear to render his declaration incomplete. First, the declaration states that between 2013 and 2014, physicians and other providers were required to submit a CMS-855I form in order to enroll in Medicare, and that the execution of that form required providers to certify compliance with the AKS. Sendros Decl. ¶ 6. During the relevant period, CMS regulations provided that a "provider or supplier must be enrolled in the Medicare program" in order to "receive payment for covered Medicare items or services." 42 C.F.R. § 424.505. Those regulations further stated that in order to be enrolled, a provider or supplier had to have "submit[ted] enrollment information on the applicable enrollment application." *Id.* § 424.510(a). The OMB website houses the July 2011 version of the CSM-855I form that was in effect during 2013-2014.[1] That version of the form states that the submitting physician "understands that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws . . . including, but not limited to, the Federal anti-kickback statute."[2]

As Sendros acknowledged in his deposition, however, the CMS-855I form was not the only means by which physicians could enroll in Medicare at the relevant time. Sendros Dep. at 177-78. During that period, 42 C.F.R. § 424.502 defined an enrollment application as a "CMS-approved paper enrollment application or an electronic Medicare enrollment process approved by OMB." The electronic version of CMS-855I is not part of the record, and Sendros

[1] Ctrs. For Medicare & Medicare & Medicaid Servs., Form CMS-855I, *Medicare Enrollment Application: Physicians and Non-Physician Practitioners (07/11)*, (OMB No. 0938-0685), https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201105-0938-012.

[2] *Id.*

acknowledges that he has never seen that electronic form. Sendros Dep. at 179. Therefore, his declaration is incomplete as to Medicare enrollment requirements, because he cannot authenticate the contents of the electronic CMS-855I, nor can he say that the electronic form included a certification of compliance with the AKS.

Next, the declaration states that between 2013 and 2014, physicians and other submitting entities were required to submit either a paper CMS-1500 form or an electronic CMS-837P form to claim reimbursement from Medicare Part B, and that both those forms required a certification of compliance with the AKS. Sendros Decl. ¶¶ 7-9, 11. During the relevant period, the applicable regulations, 42 C.F.R. § 424.32(a)-(b), stated that "physicians and other suppliers" who wished to "request payment for medical services" were required to submit a CMS-1500 form or an electronic version. The OMB website houses both the August 2005 version of CMS-1500[3] and the February 2012 version of CMS-1500,[4] both of which were used during the relevant period.[5] The February 2012 version of CMS-1500 requires that a submitting entity certify that he or she has "complie[d] with . . . the Federal anti-kickback statute."[6] But the August 2005 version, which was apparently in effect for a portion of the relevant period, does not require such a certification. The Sendros declaration as to the contents of the CMS-1500

[3] Ctrs. for Medicare & Medicaid Servs., Form CMS-1500, *Health Insurance Claim Form* (08/05) (OMB No. 0938-0999), https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201211-0938-010.

[4] Ctrs. for Medicare & Medicaid Servs., Form CMS-1500, *Health Insurance Claim Form* (02/12) (OMB No. 0938-1197), https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201211-0938-011.

[5] OMB approved the February 2012 version of CMS-1500 on June 10, 2013. CMS began accepting claims on the revised form on January 6, 2014, but continued to accept claims using the August 2005 version of the form through March 31, 2014. Ctrs. For Medicare & Medicaid Servs., Pub. 100-04, Medicare Claims Processing, Transmittal 3083, *Form CMS-1500 Instructions: Revised for Form Version 02/12* (Change Request 8509) (Oct. 2, 2014), https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/r3083cp.pdf.

[6] *Id.*

form therefore appears to be incomplete, as it fails to account for how the form changed over time.

The declaration likewise appears to be incomplete as to the CMS-837P electronic form. During the relevant period, the relevant regulation stated that submission of electronic claims was required except in certain unusual cases. 42 C.F.R. § 424.32(d)(2)-(4). But the regulation does not specifically name the CMS-837P form; the government has not submitted the form in evidence;[7] and OMB does not appear to house the form on its website. Moreover, Sendros testified that he has not seen the electronic form, and acknowledged that a provider does not have to make an express certification of compliance with the AKS when submitting a claim electronically using the 873P format. Sendros Dep. at 249-50. Therefore, his statement that the CMS-837P form serves as the "electronic equivalent" to CMS-1500 is not sufficient to establish what the contents of the CMS-837P form were, and specifically whether the form included an express certification.

Third, the declaration states that during the relevant period, providers were required to submit the CMS-10164B EDI form along with a CMS-837P form, and that the EDI form stated that providers would be subject to penalties if they violated federal law. Sendros Decl. ¶ 10. Again, however, that declaration appears to be at least somewhat incomplete. The declaration states that "Medicare Administrative Contractors ("MACs") may use their own organization-

[7] The government contends that it was not required to submit a copy of the CMS-837P form. That is incorrect. The best evidence rule provides that "[a]n original writing or record is required in order to prove its content unless these rules or a federal statute provides otherwise." Fed. R. Evid. 1002. Fed. R. Evid. 1001, in turn, defines "writing" as consisting of "letters, words, numbers, or their equivalent set down in any form" and "recording" as "letters, words, numbers, or their equivalent recorded in any matter." A CMS-837P form is a "writing" or "recording" because it is simply words transposed onto an interactive electronic form, and could have easily been downloaded or otherwise included in the record. *See, e.g.*, *United States v. Bennett*, 363 F.3d 947, 952-55 (9th Cir. 2004) (striking law enforcement officer's testimony about a boat's travel path based on GPS data he had observed, as neither the actual data nor a direct recording of it had been introduced into evidence).

specific EDI enrollment form" that is "comparable in terms of content." Sendros Decl. ¶ 10 n.1. But, Sendros acknowledged that he has never reviewed a specific EDI enrollment form issued by a MAC, and those documents do not appear to be housed on the OMB website. Sendros Dep. at 341. Therefore, the evidence in the record does not appear to include the contents of all EDI enrollment forms.

Finally, the declaration states that compliance with the AKS was material to CMS's payment decisions. Specifically, Sendros stated as follows:

> I . . . am familiar with CMS rules and regulations, including payment policies, and I am aware that CMS takes compliance with the AKS very seriously. Even when the underlying services or products are otherwise medically necessary, CMS's position is that it will not pay for such services or products if they were delivered in manner that does not comply with the AKS. In other words, compliance with the AKS is material to CMS's payment decision.

Sendros Decl. ¶ 3.

Defendant contends that the statement should be struck because Sendros was not present at CMS during the period from 2013 to 2014, and therefore does not have personal knowledge of its payment policies during that period.

As set forth in greater detail below, it seems obvious that the submission of a claim for medical services that arises out of the payment of a kickback to a provider would always be material to the payment approval decision. And even if CMS paid the claim regardless, an AKS violation is certainly capable of influencing that decision. Nonetheless, the Supreme Court has held that the materiality standard in this context is "demanding," that the government must put forth some level of evidentiary proof of materiality, and that the payment of any particular claim despite knowledge of an AKS violation, is "very strong evidence" that AKS compliance is not material. *See Universal Health Servs., Inc., v. United States ex rel. Escobar*, 579 U.S. 176, 194-

95 (2016). Under the circumstances, the Sendros declaration falls short of conclusively establishing materiality for the time period 2013 to 2014.

Nonetheless, that does not require that the declaration be struck. His testimony concerns current practices at CMS—it is written in the present tense—and he appears to have personal knowledge of those practices. At worst, his declaration is incomplete or only marginally relevant, but it is not improper and need not be struck.

In summary, the amended Sendros declaration, along with the government's other evidence as to Medicare processes and forms, appears to be at least somewhat incomplete, but need not be struck. The Court will therefore deny defendant's motion to strike the amended declaration.

B. The Government's Motion for Partial Summary Judgment

The government has moved for partial summary judgment on three issues: (1) an issue underlying the element of falsity—specifically, that every Eylea claim submitted for Medicare Part B reimbursement between 2013 and 2014 included a representation of compliance with the AKS; (2) the element of materiality—specifically, that AKS violations are always material to the payment of claims; and (3) the applicable legal standard for causation in a false certification case—specifically, that the government need not prove but-for causation.

1. Falsity

First, the government contends that it is entitled to summary judgment on an issue underlying the element of falsity. In order to establish falsity under the false certification theory, the government must prove that (1) claims submitted to the government contained either express or implied representations of compliance and (2) those representations were false. *See Regeneron*, 128 F.4th at 333-34; *Escobar*, 579 U.S. at 186-90. The government seeks summary judgment as to the first of those issues—specifically, that every Eylea claim submitted to

Medicare Part B between 2013 and 2014 contained a representation of compliance with the AKS.

Under the express false certification theory, a claim is false when the "entity seeking payment certifies compliance with a law, rule or regulation as part of the process through which the claim for payment is submitted" and that claim is false. *Ebeid ex rel. U.S. v. Lungwitz*, 616 F.3d 993, 998 (9th Cir. 2010); *see also United States ex rel. Mackillop v. Grand Canyon Educ., Inc.*, 626 F. Supp. 3d 418, 446 (D. Mass. 2022) ("A claim is legally false under an express certification theory when the party making the claim for payment expressly represents compliance with a statute or regulation."). Under the implied false certification theory, a claim is false when it "makes specific representations about the goods or services provided," and "the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half truths." *Escobar*, 579 U.S. at 190.

Defendant first contends that the government's motion will not materially advance the disposition of the case because, on either theory, the government must still prove falsity by showing that the certification was knowingly false when made. Therefore, even if every claim for Medicare reimbursement was accompanied by an explicit or implicit certification that the provider had complied with the AKS, that would not suffice (according to defendant) to render claims false where, as here, the providers (that is, the physicians) had no involvement in or knowledge of the alleged AKS violation.

The Court disagrees. In *U.S. ex rel. Hutcheson v. Blackstone Med., Inc.*, the First Circuit assessed an FCA claim where plaintiff alleged that defendant had paid kickbacks to physicians so that they would use its products in certain spinal surgeries. 647 F.3d 377, 380 (1st Cir. 2011). The court explicitly rejected the argument that the person or entity who submitted the claim had

to have at least known about the AKS violation, stating that "unlawful acts by non-submitting entities may give rise to a false or fraudulent claim even if the claim is submitted by an innocent party." *Id.* at 390 (referring to the submitting party as "unwitting," *id.* at 378). Indeed, the *Hutcheson* court stated that whether "hospitals knew of the underlying kickbacks" had "no bearing on [defendant's] potential liability under the FCA." *Id.* at 393 (also stating that requiring hospitals to know of underlying kickbacks would "systematically excuse from FCA liability non-submitting entities who cause the submission of claims that fail to meet that stated precondition"). Thus, under the false certification theory, it is irrelevant whether the submitting physician, who certified compliance, knew that the claim arose from an AKS violation.

The question remains whether every Eylea claim submitted between 2013 and 2014 indeed contained an express or implicit representation of compliance with the AKS. The government has not submitted evidence of any actual Eylea claims submitted during that time period. Instead, the government (1) relies on the Sendros declaration, which, as noted, generally describes the form requirements for physician participation in and reimbursement from Medicare during the period between 2013 and 2014, and (2) examples of those forms (specifically, the CMS-855I, 1500, 837P and 10164B forms).

That is not a sufficient basis to grant summary judgment on the issue of certification of compliance. It is true that Section 15 of the CMS-855I form states that submitting entities "understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws . . . including, but not limited to, the Federal anti-kickback statute." However, and as noted, physicians could also submit an electronic version of that form, and there is no evidence before the Court as to the contents of that form.

Thus, the Court cannot conclude that every enrollment form submitted between 2013-2014 contained certifications of compliance with the AKS.

As to the CMS-1500 form, it is true that the February 2012 version that came into effect in January 2014 states that the claim must "compl[y] with all applicable Medicare . . . laws . . . including [the AKS]." However, as explained above, the previous version of that form did not contain such a certification. Moreover, physicians were allowed to submit the electronic CMS-837P form, and the contents of that form are not in evidence. The Court thus cannot conclude that the CMS-837P form included compliance language such that all physicians who claimed reimbursements had to certify compliance with the AKS.

That leaves the CMS-10164B form. That enrollment form states that "anyone who misrepresents or falsifies or causes to be misrepresented or falsified any record or other information relating to that claim . . . may . . . be subject to [punishment] under applicable Federal law." But as Sendros also acknowledges, "Medicare Administrative Contractors ("MACs") may use their own organization-specific EDI enrollment form." Sendros Decl. ¶ 10 n.1. And although a MAC form must be "comparable in terms of content," Sendros acknowledged that he has never reviewed a specific EDI enrollment form issued by a MAC. Sendros Dep. at 341. Therefore, the Court cannot conclude that every physician who submitted an Eylea claim during the period from 2013 to 2014 attested to the certification on a CMS-10164B form.

Accordingly, the Court will deny the government's motion for partial summary judgment on one of the issues of falsity—that every claim for Eylea submitted to Medicare Part B between 2013 and 2014 contained a representation of AKS compliance.

2. Materiality

The government next contends that it is entitled to summary judgment on the issue of

materiality because (1) compliance with the AKS is material as a matter of law and (2) in any event, there is no genuine factual dispute that AKS compliance is material. Based on the Supreme Court's articulation of the standard for materiality under the FCA, summary judgment as to that issue will be denied.

As noted, and as a matter of common sense, it seems highly likely that CMS would refuse to pay any claim that arises from the payment of a kickback to a provider. And even if, on occasion, it elected to do so, it is hard to imagine a scenario under which an AKS violation was not at least *capable* of influencing the decision to pay the claim, and therefore material.

It is also true that courts have found—apparently without exception—that alleged AKS violations are likely to be material. *See, e.g., Hutcheson*, 647 F.3d at 394 (stating, in the context of reviewing the sufficiency of a complaint, that "[it] [could not] say that, as a matter of law, the alleged misrepresentations in the hospital and physician claims were not capable of influencing Medicare's decision to pay the claims"); *Guilfoile*, 913 F.3d at 189-91 (reading the 2010 amendment to the AKS, which does not include materiality language, to "obviate[e] the need for a plaintiff to plead materiality" because it "essentially codifie[d] the long-standing view that AKS violations are 'material' in the FCA context" (collecting cases)).

Nevertheless, the Court cannot find that AKS violations are material as a matter of law. In *Escobar*, the Supreme Court stated that the materiality standard is "demanding," and that the FCA is "not an all-purpose antifraud statute." 579 U.S. at 194 (citation omitted) (rejecting the First Circuit's materiality standard which had held that "any statutory, regulatory, or contractual violation [was] material so long as the defendant k[new] that the Government would be entitled to refuse payment were it aware of the violation," *id.* at 195). Therefore, "[a] misrepresentation cannot be deemed material merely because the Government designates compliance with a

particular statutory, regulatory, or contractual requirement as a condition of payment." *Id.* Instead, the government must put forth "proof of materiality[, which] can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the [AKS]." *Id.* at 194-95. That evidence is rebuttable. "[I]f the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material." *Id.* at 195. Moreover, "if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material." *Id.* Accordingly, the issue of materiality under the FCA is a question of fact.

The government further contends that it is entitled to summary judgment on the issue of materiality because there is no genuine dispute of material fact as to that issue.[8] The government puts forth three contentions. First, the government contends that (1) the terms of CMS-855I during the relevant time required compliance with the AKS; (2) every claim for Eylea submitted by means of a CMS-1500 form required compliance with the AKS; and (3) every claim for Eylea submitted electronically by means of a CMS-837P form also required a certification in the CMS-10164B form that the claim was true, accurate, and complete. Second, the government points to the Sendros declaration, which states that compliance with the AKS is material to CMS's payment decisions. Finally, the government notes that several AKS-FCA lawsuits have

[8] As to the government's burden of proof, defendant contends that the government must prove that CMS would decline to pay for the particular medical treatment if it knew of the particular AKS violation. That is incorrect. As set forth by the *Escobar* court, the government must put forth proof that CMS declines to pay claims in the "mine-run" or routine, average case of non-compliance with the AKS. *Escobar*, 579 U.S. at 194-95. Defendant may rebut that with evidence of a particular claim where CMS has paid regardless of the AKS violation. *Id.* at 195.

recovered billions of dollars, which indicates that the government regularly enforces the AKS and pursues FCA liability based on such violations.

First, the government's argument concerning the CMS forms is relevant, but not dispositive, as to materiality. As noted in *Escobar*, "the Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive." *Id.* at 194. Therefore, the fact that the CMS-1500, 873P, and 10164B forms may have required certification of AKS compliance does not mean that non-compliance was categorically material.

Second, as noted, Sendros's statements that compliance with the AKS is material to CMS's payment decision addresses only current practices, not the practice in the period from 2013 to 2014. There is also at least some question as to whether it would be enough to meet the Supreme Court's evidentiary standard, even if it addressed historical practices, in light of the requirements of *Escobar*.

Finally, settlements in other AKS-FCA co-pay assistance charity cases do not necessarily indicate that such violations are material. The government and the defendants may have agreed to settle those claims for a host of reasons, none of which have any legal effect.

The Court will therefore deny the government's partial motion for summary judgment as to materiality.

3. Standard for Causation

Finally, the government contends that it does not need to prove but-for causation in a false certification case. Instead, the government contends that it need only demonstrate that defendant's conduct naturally and foreseeably caused providers to present false claims for Eylea under 31 U.S.C. § 3729(a)(1)(A), or that it naturally and foreseeably caused a provider to make or use such a false record or statement material to a claim under 31 U.S.C. § 3729(a)(1)(B).

The Court agrees, although the caselaw on this issue is admittedly muddled. The government first contends that the First Circuit, in *Regeneron*, has already held that but-for causation is not required in false certification cases. There, the court analyzed the 2010 amendment's "resulting from" language to determine whether but-for causation was required to prove falsity. *Regeneron*, 128 F.4th at 336. Specifically, the court assessed whether the government was required to prove that an AKS violation "actually caused" a physician to provide different medical treatment and thus submit a false claim. *Id*. at 327. Finding no reason to depart from the default principle that causality language "imposes a requirement of but-for causation," the court held that the government must show that an "illicit kickback was the but-for cause of a submitted claim." *Id.* at 329, 336.

The government notes, correctly, that when assessing whether the 2010 amendment modified the false certification theory, the *Regeneron* court stated that "there [was] nothing in the 2010 amendment that require[d] proof of but-for causation in a false certification FCA case." *Id.* at 333. But that is because the false certification theory, by its own terms, does not require but-for causation analysis to determine falsity, as "it is not the AKS violation itself that renders the claim false." *Id.* "Rather, it is the false representation that there is no AKS violation." *Id.* Therefore, under that pathway, the government does not have to prove that the AKS violation was a but-for cause of the item or service to prove falsity (as it must do under the 2010 amendment). Instead, it must demonstrate "material misrepresentation of compliance with the AKS." *Id.*

Under the terms of § 3729(a)(1)(A) and § 3729(a)(1)(B), a person can materially misrepresent compliance with the AKS in two ways. A person can personally present claims, or make or use statements material to claims, that misrepresent compliance. 31 U.S.C. §

3729(a)(1)(A), (B). Or the person can "cause[]" healthcare providers to present claims, or "cause[]" healthcare providers to make or use statements material to claims, that misrepresent compliance. *Id.* As both parties acknowledge, this case falls into the latter category. The question, then, is whether the government must prove that defendant's conduct was the but-for cause of providers submitting claims or making statements material to claims that misrepresented compliance with the AKS.

Proof of but-for causation, specifically in the context of § 3729(a)(1)(A) and § 3729(a)(1)(B) in false certification cases, is not required. To be sure, the term "cause" may impose "a requirement of actual causality." *Burrage v. United States*, 571 U.S. 204, 211 (2014). "In the usual course, this requires proof that the harm would not have occurred in the absence of—that is, but for—the defendant's conduct." *Id.* (citation modified) (quoting, inter alia, Restatement of Torts § 431, Comment *a* (1934)). However, a "default assumption" is not an "immutable rule." *Regeneron*, 128 F.4th at 329. "A court may read [causality language] to impose an alternative causation standard if there are 'textual or contextual indication[s]' supporting that approach." *Id.* (quoting *Burrage*, 571 U.S. at 212).

There are such contextual indicators here. Specifically, requiring but-for causation would superimpose the 2010 amendment's requirements onto the false certification theory. As the government notes, CMS reimburses claims by procedure code. That means that when physicians submit a claim, they do so for a specific procedure. If the Court were to require but-for causation, it would require the government prove that but for the defendant's conduct, the physician would not have submitted the claim for the medical procedure—in other words, if not for the AKS violation, the medical procedure would not have occurred. That is exactly the

government's burden under the 2010 amendment, which requires government to prove that item or service "resulted from" the AKS violation.

That conflation might be permissible if the 2010 amendment were intended to codify pre-2010 practice in false certification cases. But that is not so. Prior to the 2010 amendment, courts reasoned that "'compliance with federal health care laws, including the [AKS], [was] a condition of payment by' Medicare." *Cairns*, 42 F.4th at 835 (quoting *McNutt ex rel. United States v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1259 (11th Cir. 2005)). Therefore, "any failure to disclose an anti-kickback violation—regardless of the relationship between the illegal kickbacks and the items or services included—was sufficient." *Id.* (citing *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 313 (3d Cir. 2011) (emphasis removed). As the Eighth Circuit has noted, if Congress wanted to "codify" those pre-2010 false certification cases, "it could have selected different language." *Id.* at 836. Instead, Congress added the new but-for causation language in order to close a major loophole that allowed healthcare fraud schemes to often escape penalties if an innocent third party had submitted the claim.

Accordingly, the government's burden under the false certification theory is not to prove but-for causation, but instead to prove that the submitted claim (or statement material to the submitted claim) was the reasonably foreseeable result of the defendant's conduct. In determining that to be the appropriate standard, the Court looks to First Circuit authority which suggests, although does not directly hold, that this is how the circuit interprets the causal language in § 3729. *See, e.g.*, *U.S. ex rel. Hutcheson v. Blackstone Med., Inc.*, 694 F. Supp. 2d 48, 61-62 (D. Mass. 2010), *rev'd on other grounds*, 647 F.3d 377 (1st Cir. 2011) (citing *U.S. ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 733 n.9 (1st Cir. 2007) ("[T]he 'causes to be presented' prong of the False Claims Act, results when the submission was the reasonably foreseeable result

of a defendant's actions."); *Rost*, 507 F.3d at 733 n.9 ("under the [FCA] . . . [t]hat there were allegedly intervening persons who actually submitted the claims does not itself necessarily break the causal connection when the claims are foreseeable"); *see also Hutcheson, Inc.*, 647 F.3d at 393-94 (1st Cir. 2011) (rejecting defendant's argument that physician claims "were not false or fraudulent because the claims were for services that would have been provided in the absence of the alleged AKS violations" because "[i]f kickbacks affected the transaction underlying a claim . . . the claim failed to meet a condition of payment.").

As a final note, although the government seeks partial summary judgment as to the standard of causation, it in fact is not seeking judgment in its favor as to any claims, or any element of a claim, on that basis; rather, it is simply seeking a legal ruling as to the interpretation of the relevant statute. Accordingly, while the Court agrees with the government's interpretation, it will not grant summary judgment in the government's favor as to that issue.

IV. Conclusion

For the foregoing reasons, the motion of Regeneron to strike Dennis Sendros's amended declaration is DENIED. The motion of the United States for partial summary judgment is GRANTED, to the extent that the United States sought a legal ruling that it need not prove but-for causation under the false certification theory of liability under 31 U.S.C. § 3729(a)(1), and is otherwise DENIED.

So Ordered.

/s/ F. Dennis Saylor IV
F. Dennis Saylor IV
United States District Judge

Dated: November 19, 2026