UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

| UNITED STATES OF AMERICA ex rel. ANDREW SHEA, |))) |
|---|----------------------------------|
| Plaintiff, | Civil Action No. 21-cv-11777-DJC |
| v. | Hon. Denise J. Casper |
| eHEALTH, INC., et al., |) |
| Defendants. |) |
| |) |

REPLY IN FURTHER SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE GOVERNMENT'S COMPLAINT IN PARTIAL INTERVENTION

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INTRODUCTION

The Government's opposition illustrates the perils of using litigation as a substitute for regulation. Despite CMS's years-old regulations governing payments from MAOs to TPMOs, the Government's AKS-based FCA theory proceeds as if those regulations—which permit payments "based on" enrollments so long as they do not exceed fair market value—do not matter. And the Government does not even try to square its position that "marketing" is allowed but "steering" is not with the reality that CMS repeatedly has stated that legal "[m]arketing is the act of steering." Infra p. 14 n.7. The Government also seeks to pioneer a discrimination-based FCA theory in which—contrary to law—(i) it need not identify a single beneficiary who faced discrimination and (ii) it can treble liability for claims that were not submitted. Under both theories, the Government fails to identify any instance in which it refused to pay MAOs based on similar supposed violations for payments CMS has been closely monitoring for decades. Nor does it explain how any claim Defendants did submit was caused or tainted by a legal violation. Instead, the Government retreats to the absurd position that the Court should hold Defendants liable for every single claim submitted by the largest companies in the MA industry over a five-year period.

For these and other defects, the Complaint must be dismissed. The Government presumes otherwise, but the FCA is not an "all-purpose" vehicle to police all manner of perceived infractions. *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 579 U.S. 176, 194 (2016).

ARGUMENT

- I. THE GOVERNMENT FAILS TO PLEAD AKS-BASED FCA CLAIMS.
 - A. The Government Fails to Plead a Violation of the AKS.
 - 1. The Government's Theory Cannot be Reconciled with CMS's Regime for Administrative Payments.

The Government complains that Defendants "assail[] a case that the Government did not

¹ All emphasis is added, quotations cleaned up, and citations omitted unless otherwise noted.

bring." Opp. 2. This highlights the problem: the Government's case ignores the regulatory structure CMS enacted to govern the payments at issue here and skips directly to the AKS. The Complaint fails to allege any violation of the CMS regulations, let alone of the AKS. That is, the Government never explains how fair market value administrative payments that are lawful under the framework established by the purportedly defrauded agency, CMS, transform into criminal remuneration under the AKS once DOJ gets involved. Because the Government has not pled an AKS violation, it has not pled an FCA violation.² Counts I, II, and IV must be dismissed.

i. CMS Regulations Allow Fair Market Value Administrative Payments.

It is undisputed that Congress contemplated that payments from MAOs to TPMOs would be used to "incentiv[ize]" broker behavior regarding beneficiary enrollment. Mot. 6. CMS, in turn, promulgated regulations that divide these payments into two categories:

- 1. enrollment compensation (by definition, payment *for* an enrollment) capped at a dollar amount, *see*, *e.g.*, 42 C.F.R. § 422.2274(a)(1)(i)–(ii) (version effective Nov. 14, 2008); and
- 2. "payments other than compensation (administrative payments)" (which can be *based on* enrollments) capped at "fair-market value" for those services, *id.* § 422.2274(a)(1)(iv); *see* Mot. 8.

Given this regulatory structure, the Government agrees that enrollment compensation—a payment expressly *for* an enrollment—is lawful when consistent with the regulation's dollar cap. If that portion of CMS's regulation shields enrollment payments from the AKS when at or below the dollar cap, the subsequent subsection of the same regulation must also shield administrative (*e.g.*, marketing) payments *based on* enrollments from the AKS when at or below the fair market cap. But the Government resists this inescapable conclusion because, as it concedes (Opp. 10–12), it

² Among other things, the Government fails to plead that claims were "false" because it ignores the regulations allowing the challenged payments. In addition to that defect, the Government mistakenly states that Defendants do not challenge the Complaint's scienter allegations. Defendants' opening explains how the Complaint fails to plead knowing and willful noncompliance with CMS's marketing regulations. Mot. 13–16.

has not alleged that any of the administrative payments exceeded fair market value. Undeterred, the Government claims the payments it challenges were unlawful because they were "in part" for enrollments. *Id.* at 10. The Government does not articulate where the line is between the "part" of the payments that were for (concededly permissible) marketing services and the "part" allegedly for enrollments. *See*, *e.g.*, Compl. ¶¶ 54–59, 587 (acknowledging Defendants "advertised"). But CMS *did* draw that line, it did so at fair market value, and the Government has no answer.

As the Government recognized in the Texas litigation, CMS used the fair market value standard to police what makes up the core of the Government's theory here: use of administrative payments to evade the enrollment commission cap. Mot. 21–23. The Government runs from the Texas case, wrongly asserting that this Court may not consider it. Opp. 8 n.1; *Staehr v. Hartford Fin. Servs. Grp., Inc.*, 547 F.3d 406, 426 (2d Cir. 2008) (courts may notice "assertions ... made in lawsuits"); *see Kowalski v. Gagne*, 914 F.2d 299, 305–06 (1st Cir. 1990). Further, the history of CMS's regulations itself shows fair market value was meant to stop evasion of the dollar cap for enrollment commissions. *See* 42 C.F.R. § 422.2274(a)(1)(iv) (2008); *id.* § 422.2274(b)(1)(iii)(B) (2018); *Medicare Advantage and Prescription Drug Benefit Programs*, 76 Fed. Reg. 54,600, 54,622 (Sept. 1, 2011) (describing "fair-market value cut-off[s]" as an enforcement mechanism). Because the Government fails to allege that any payment exceeded fair market value, it has not pled a violation of the CMS regulations, let alone the AKS or the FCA.

ii. The Government Fails to Plead Unlawful Remuneration.

For similar reasons, the Government has not pled "remuneration" under the AKS. Mot. 21–23. The Government cites *United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 33 (1st Cir. 1989) for the proposition that it need not plead that payments exceeded fair market value. Opp. 11. But, as Defendants have noted (Mot. 22 n.6), that case did not involve regulations *authorizing* payments if they were fair market value. The Government cites *Guilfoile*

v. Shields, 913 F.3d 178 (1st Cir. 2019) (Opp. 11) for the view that "[t]here is no fair market value for kickbacks." Not only does that case not address fair market value, but the cited statement aligns with the reversed proposition that Defendants and CMS propound: payments for enrollment and administrative payments that *are* fair market value *are not* kickbacks as a matter of law.

The Government's citation (Opp. 12) to U.S. ex rel. Westmoreland v. Amgen, Inc., 812 F. Supp. 2d 39 (D. Mass. 2011) further undercuts its position. Westmoreland did not address whether a plaintiff in an AKS-based FCA case must plead payments exceeded fair market value. Rather, the court found that overfill in vials of medication had "no independent value" for purpose of AKS liability. 812 F. Supp. 2d at 68. In construing the AKS, the court cited the preceding section of Title 42 (the Civil Monetary Penalties ("CMP") law) for the proposition that "remuneration" is defined as "transfers of items or services for free or other than *fair market value*." *Id.* (quoting 42 U.S.C. § 1320a-7a(i)(6)). It is nonsensical to think, as the Government suggests, that a higher bar exists to establish remuneration for civil liability under the CMP law than to establish criminal liability under the AKS. Indeed, the AKS dictates otherwise: the AKS does not prohibit all remuneration, just "remuneration" "in return for referring." § 1320a-7b(b)(1)(A). Administrative payments that are fair market value do not fall within that language because they are, by definition, for a service, not a referral. This is why the cases cited by Defendants, but mostly ignored by the Government, have held the Government must allege that the challenged payments exceeded fair market value. Mot. 21–22.³ The Government's failure to do so here requires dismissal.

iii. The Government Ignores Defendants' Argument that CMS

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³ The Government suggests (Opp. 12) that the Eleventh Circuit has discarded *Bingham v. HCA*, *Inc.*, 783 F. App'x 868, 873 (11th Cir. 2019), but the case cited by the Government *was not an AKS case* and addressed an irrelevant aspect of *Bingham*. *See U.S. ex rel. Sedona Partners LLC v. Able Moving & Storage Inc.*, 146 F.4th 1032, 1041 (11th Cir. 2025). The Government also tries to skirt *U.S. ex. rel. Millenium Laby's, Inc.*, by arguing it was about the first-to-file rule (Opp. 12), but ignores that in evaluating whether one of the relator's complaints "alleged the essential elements [the] kickback scheme" and finding it did not, the First Circuit held that the earlier filing relator "did not allege that [the price] was less than fair market value." 923 F.3d 240, 254 (1st Cir. 2019).

Allows Administrative Payments "Based On" Enrollments.

CMS has long authorized marketing payments "based on" enrollments, so long as they are fair market value. Mot. 15 (citing 42 C.F.R. § 422.2274 (2021)). The Government never explains how the marketing payments were anything other than "based on" enrollments and simply declares that the payments were "for" enrollments (and thus subject to the enrollment compensation dollar-cap). Mot. 15. But the Complaint itself acknowledges that enrollments can be used as a "proxy" for fair market value—a passing yet key concession that fair market value matters—and never otherwise addresses the issue or pleads facts supporting that the payments here were anything other than (lawfully) "based on" enrollments. *Id.* (citing Compl. ¶ 81). The Government does not respond to Defendants' argument that these marketing payments were (of course) designed to lead to enrollments and that it is both permitted and expected that corresponding marketing budgets would be "based on" enrollments. In failing to address this, the Government has waived any objection. *Eldridge v. Gordon Bros. Grp., L.L.C.*, 863 F.3d 66, 83 (1st Cir. 2017).

The Government's non-answer helps illustrate why its due process defense falls flat. The Government brushes off due process concerns because it says (a) CMS made clear that payments "based on" enrollments are allowed and payments "for" enrollments are not, and (b) Defendants were "sophisticated companies [with] actual knowledge of the AKS." Opp. 23–26. But without a clear demarcation of the "based on" versus "for" line, it is absurd to suggest Defendants should have known where DOJ felt this line was or that it was unreasonable to follow CMS regulations that treated fair market value as the line. *See United States v. Gilead Scis., Inc.*, 2025 WL 2627686, at *13 (E.D. Pa. Sept. 11, 2025) ("tautological" to argue regulated conduct "can become illegal kickbacks" without establishing regulatory violation). Nor did Defendants have notice that crossing this made-for-litigation line would violate the AKS. The Government's fallback argument that the regulations do not "use[] the term 'marketing'" so there could not have been

misleading guidance (Opp. 24) is disingenuous, as CMS has issued "Marketing Guidelines" on a near-yearly basis. Mot. 14; *see United States v. Facteau*, 89 F.4th 1, 35 (1st Cir. 2023).

2. The Government Fails to Allege Prohibited Inducement.

The Government admits that "inducement" under the AKS requires it to plead facts that, if proved, would show that the challenged payments were used "to *improperly* influence decisions on the provision of health care." Opp. 13. But it fails to grapple with Defendants' core argument, Mot. 24–25, that the Government's allegations of inducement fail to distinguish kickbacks (which by definition aim to influence) from lawful marketing (which also aims to influence).

The Government says AKS inducement is present simply because the TPMOs were in a "position to generate [health care] business." Opp. 13–14. But that does not allege "improper[]" influence, which the Government admits is needed. *Id.* at 13. Otherwise, a pharmaceutical company would violate the AKS every time it paid an advertiser to run a commercial for a reimbursable drug. Instead of grappling with the sweeping ramifications of its position, the Government claims to find support in *Guilfoile* (Opp. 14). But that case says only that the ability to generate business is one of several "relevant considerations." *Guilfoile*, 913 F.3d at 189.

The courts that *have* distinguished kickbacks from lawful marketing payments have appreciated that applying the AKS to marketing is often a stretch. In *United States v. Sorensen*, the Seventh Circuit observed that in the "typical example" of a "physician who accepts money" to refer patients, the AKS violation is clearer because a physician has near-total control of a patient's decisions and the payment—unlike payment to a marketer—affords "no other [lawful] benefit to the payor." 134 F.4th 493, 499–500 (7th Cir. 2025). *Sorensen* held that, while a non-physician marketer can be liable if a physician rubber stamps the marketer's suggestions, "advertising" that left intact the consent of the relevant decisionmakers does not violate the AKS. *Id.* at 500–04; *see United States v. Marchetti*, 96 F.4th 818, 827 (5th Cir. 2024) (similarly reasoning "not every sort

of influence is improper" only "improper" influence; "What are advertisers hired to do anyway?").

Here, the Government does not plausibly allege that anyone was unduly influenced by the TPMOs. Rather, the Complaint accepts that beneficiaries made the final call on their enrollment decisions and were enrolled only with their "consent." Compl. ¶ 58. In fact, the Complaint notes that beneficiaries often enrolled online, without ever even *speaking* with the TPMOs. *Id.* The Government alleges that TPMOs listed only certain carriers or wanted to "increase sales." Opp. 15. But TPMOs have no legal obligation to carry or sell all plans, *see*, *e.g.*, Compl. ¶ 53; Mot. 6, and a desire to increase sales is both entirely natural to lawful marketing and says nothing about whether the TPMOs here exerted physician-like influence. The Government merely protests that *Sorensen* is wrong and invites this Court to open a circuit split. Opp. 14.

The Government resorts to quoting a CMS proposed rule issued on May 16, 2008. *Id.* 15. The proposed rule says TPMOs can "influence beneficiary choices," but does not explain why the particular remuneration the Government alleges here was in fact improper inducement. The proposed rule also *predates* the CMS rules authorizing fair market value payments for marketing and was accompanied by CMS *defining* lawful "marketing" as "the act of steering." *Revisions to the Medicare Advantage and Prescription Drug Benefit Programs*, 73 Fed. Reg. 28,556, 28,582 (May 16, 2008). CMS's own actions thus refute the Government's assertion that it is "beside the point that the [MAOs] may have also paid [the TPMOs] ... to market." Opp. 16. Because marketing is lawful and, as CMS has acknowledged, done to influence beneficiary decisions, the Government must do more than allege that TPMOs could "influence" beneficiaries.

3. MA Plans and Enrollments Are Not "Goods," "Services," "Items," or a "Facility," as Required to Implicate the AKS.

The Government does not dispute Defendants' argument that enrollments in an MA plan do not constitute a "good," "item," "service," or "facility" as required to implicate the AKS. Mot.

16–17 (citing 42 U.S.C. § 1320a-7b(b)(2)). The Government now claims that its theory is only that MA plans themselves are an "item" or a "service." Opp. at 16–17.⁴

The Government's primary theory is that handpicked dictionary definitions of the words "item" or "service" can be stretched to encompass MA plans. *Id.* at 17–18. That reading runs afoul of a basic principle: courts interpreting the "plain meaning" of a statute do not merely apply dictionary definitions word-by-word, but rather "focus on the plain meaning of the *whole* statute, not of isolated sentences" or phrases. *Colón-Marrero v. Vélez*, 813 F.3d 1, 11 (1st Cir. 2016). As Defendants have noted (Mot. 19), every time the Social Security Act refers to "item" and "service," it refers to things provided to patients as part of their medical care. *See*, *e.g.*, 42 U.S.C. § 1395x.

Context reinforces this reading. The AKS safe-harbor regulation defining the terms "item" and "service" makes clear those terms *do not* capture "[m]arketing and other pre-enrollment activities." 42 C.F.R. § 1001.952(t)(2)(iv); Mot. 18–19. The Government argues this regulation is "irrelevant" because it states that its definitions apply only to that section. Opp. 22. But "there is a natural presumption that identical words used in different parts of the same act are intended to have the same meaning." *Atl. Cleaners & Dyers, Inc. v. United States*, 286 U.S. 427, 433 (1932).

The Government's theory that the MA plan is the "item" or "service" also tortures the text by creating a nonsensical loop. The statute states the AKS applies to "item[s] or service[s]" only if they are also something "for which payment may be made in whole or in part under a Federal health care program," 42 U.S.C. § 1320a-7b(b)(2), which the AKS defines as the "plan or program that *provides health benefits*, whether directly, through insurance, or otherwise." § 1320a-7b(f). Because MA plans are "federal health care program[s]," they cannot also be an "item" or "service"

⁴ The Government does not dispute that a plan is not a "facility." In a footnote, the Government says a plan "may" be a "good," but—citing no cases—does not develop this. Opp. 18 n.3.

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paid for by such programs. The only plausible reading is that the AKS covers payments from the federal healthcare program for items or services billed pursuant to the program. *See United States v. Regeneron Pharms.*, *Inc.*, 2020 WL 7130004, at *7 (D. Mass. Dec. 4, 2020). That reading also repudiates the Government's hyperbolic suggestion that Defendants' argument would remove everything related to MA from the ambit of the AKS. Opp. 21.

The Government has no answer to this circularity. The Government suggests "Medicare" may be the relevant "federal health care program," *id.* 16, but that is wrong; in the MA program, Medicare does not provide health or insurance benefits and instead authorizes CMS to contract with MAOs to provide those benefits. Mot. 4–5. Side-stepping the issue, the Government claims an out-of-Circuit district court decision "determined that a [MA] plan is an 'item or service' under the AKS," Opp. 19, but that decision was in a securities matter where the defendants did not contest whether an MA plan is an "item" or "service." *See Bond v. Clover Health Invs., Corp.*, 587 F. Supp. 3d 641, 657–58, 663 (M.D. Tenn. 2022). The same goes for *U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295 (3d Cir. 2011) (Opp. 19), where the defendant contested the AKS claims on other grounds and so the court did not ask if a plan could be an item or service.

Finally, the Government unsurprisingly cites nothing in the legislative history to undercut the reality that Congress intended to cover healthcare-related items or services—not the programs themselves. Mot. 20. Notably, the MA program did not even exist at the time the AKS was passed. Because MA Plans are not "items" or "services," the AKS-based claims must be dismissed.

- B. The Government Fails to Plead an AKS-Based Violation of the FCA.
 - 1. Counts II and IV: The Government Fails to Plead Materiality or the Existence of Particular False Claims.
 - i. The Government Fails to Plead Materiality.

The Government does not dispute that materiality is a "demanding" requirement that cannot be met by "conclusory allegations." Mot. 26–27. Nor does it dispute that the Complaint

is replete with conclusory invocations of the word "material" without pleading any instance when CMS refused to pay MAOs because of marketing payments of the kind challenged here. *Id.* 27. Instead, the Government asks the Court to exempt it from *Escobar*'s materiality analysis and find that *every* representation of compliance with the AKS is "material as a matter of law," no matter the nature of the supposed violation or what CMS knew or authorized. Opp. 30–31.

That argument is foreclosed by *Regeneron*. The First Circuit has identified two paths to pleading an FCA claim predicated on an AKS violation. Only one path allows materiality to be established as a matter of law: *If* the Government can show that specific claims "result[ed] from" kickbacks under 42 U.S.C. § 1320a-7b(g), then those are "per se false claim[s]," *United States v. Regeneron*, 128 F.4th 324, 327 (1st Cir. 2025). If (as here, *infra* p. 15) the Government cannot so plead, it "*must* show that the defendant's misrepresentation of AKS compliance was material to the government's payment decision." *Id.* at 334. The Government's own authority for its "*per se*" theory, Opp. 31, made clear that it was only "the AKS amendment"—*i.e.*, *Regeneron*'s first path—that "obviat[es] the need for a plaintiff to plead materiality." *Guilfoile*, 913 F.3d at 190. The standard applied under the second path is the one set in *Escobar*, and applied by this Court in *U.S. ex rel. Stonebrook v. Merck KGAA*, 2024 WL 1142702 (D. Mass. Mar. 15, 2024).

The Government does not deny that, under *Escobar*, "it is very strong evidence"—including in a "motion to dismiss"—that a representation is immaterial if the Government keeps paying claims despite knowledge that certain requirements were allegedly violated. *Escobar*, 579 U.S. at 195 & n.6; *see* Mot. 28. The Government claims CMS lacked knowledge of Defendants' alleged violations at the time of payment, but contradicts itself by acknowledging the broker compensation regime CMS built and monitored prior to that time—all while continuing to pay MA capitation amounts and revising regulations prospectively rather than refusing payment. Opp.

24, 30–33; Compl. ¶¶ 75–83; *see* 76 Fed. Reg. 54,600, 54,622 ("[fair market value] cut-off amounts" resulted from analyzing "historical agent and broker compensation data"). The Government even accepts that CMS authorized "certain administrative payments" from MA plans to brokers that were tied to additional enrollments. Opp. 32; *see* Mot. 28–29. These undisputed facts explain why the Government hopes to get by on boilerplate materiality recitations, but as *Escobar* teaches, that is insufficient.

The Government maintains it "regularly enforces" the AKS when it learns of violations, Opp. 32, but that is both conclusory and non-responsive to whether these violations are material. The Government relies on two irrelevant authorities that predate *Escobar*'s materiality analysis. *Westmoreland* addressed whether the AKS is a "precondition of Medicare payment," 812 F. Supp. 2d at 50, but *Escobar* made clear that is "not dispositive of the materiality inquiry," 579 U.S. at 190. And *U.S. ex rel. Bidani v. Lewis* expressly applied "the 'inducing wrongful payment' test for determining materiality" that bears no relation to the *Escobar* standard the Supreme Court adopted thirteen years later, 264 F. Supp. 2d 612, 616 (N.D. Ill. 2003). The Government ignores Defendants' authorities, which make clear that MA-related marketing violations "do not go to the essence of" any bargain because they likely do not hinder CMS's or a carrier's ability to satisfy their obligations with respect to providing insurance coverage. *U.S. ex rel. Holt v. Medicare Medicaid Advisors, Inc.*, 2022 WL 3587358, at *7 (W.D. Mo. Aug. 22, 2022); *see* Mot. 29–30.

Having alleged no impact on CMS's payment decisions, the Government resorts to boilerplate certifications, pointing to 42 C.F.R. § 422.504(a) and a catch-all clause in an MA contract. Opp. 45. But "if the Government required contractors to aver their compliance with the entire U.S. Code and Code of Federal Regulations, then under this view, failing to mention noncompliance with any of those requirements would always be material. The False Claims Act

does not adopt such an extraordinarily expansive view of liability." Escobar, 579 U.S. at 196.

ii. The Government Fails to Plead a Single False Claim.

The Government admits it must "provide details that identify particular false claims for payment that were submitted to the government," Opp. 36, which requires a "factual nexus between the underlying AKS violations and the false claims," *id.* at 34. As the First Circuit held, the Government must connect specific claims for payment to a false certification of compliance "in connection with" the supposedly AKS-violating claim. *Regeneron*, 128 F.4th at 333.

Because it is "not the AKS violation itself that renders the claim false," but a "false representation that there is no AKS violation," *id.*, the Government must be precise about what the claims and representations are. Precision eludes the Government. As to claims, the Government says there are "two types" here: (1) "enrollments"; and (2) periodic "submissions of beneficiary data." Opp. 33.⁵ But enrollments are *not* claims because they are *not* a "request ... for money or property" from a government payor and there are no certifications or representations to CMS that accompany an enrollment. 31 U.S.C. § 3729(b)(2). The Government ignores this point entirely. As to "false" representations, the Complaint alleges two: that the periodic submissions of beneficiary data (1) are "accurate, complete, and truthful" and (2) "concern[ed] 'validly enrolled' beneficiaries." Compl. ¶ 781; *see id.* ¶¶ 791–98.⁶ Thus, the falsity question here is whether the conduct that allegedly violated the AKS rendered the submitted beneficiary data: (1) inaccurate, incomplete, or untruthful; or (2) related to beneficiaries not "validly" enrolled.

The Government tries and fails to reverse-engineer a rickety link from one beneficiary

⁵ The Government mentions MA "contracts" as perhaps a third category but does not develop this. Opp. 33.

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⁶ The Government suggests all claims attested that Defendants "had not violated the AKS"—at any time, in any place—such that *any* AKS violation anywhere would globally render *all* subsequent claims false everywhere, irrespective of any link to the AKS. Opp. 35. But following the Government's citation to its source (Compl. ¶ 793), one finds a modest representation that—besides being silent on the AKS—states that a specific claim for specific enrollees contained "accurate, complete, and truthful" data on "validly enrolled" beneficiaries.

(Beneficiary 37) to a false certification. The Complaint alleges Beneficiary 37 applied to enroll in a Humana plan on February 19, 2016, and that the TPMO was eHealth. *Id.* ¶ 793. Beneficiary 37 is not mentioned again. Only in its opposition does the Government belatedly float two possible ties between an AKS violation and Beneficiary 37's enrollment: (1) "four days before Beneficiary 37's ... application," "Humana agreed to pay eHealth" to market their plans; and (2) Defendants "acknowledged ... the scheme worked." Opp. 35 (citing Compl. ¶¶ 262, 264). The Complaint itself makes no allegation connecting Beneficiary 37 to any unlawful marketing or interaction with any eHealth employee. *See* Compl. ¶ 58 (customers could enroll online without interacting with anyone). The Government now says a February 15, 2016 marketing agreement led to Beneficiary 37 applying into a Humana plan on February 19, 2016, Opp. 35, but the Complaint alleges eHealth began steering under that agreement "[a] week later" than its effective date, which was February 22, 2016—days *after* Beneficiary 37 applied. Compl. ¶¶ 262–63. Likewise, the Government's "cf." citation to a March 15, 2016 email refers to sales the month *after* Beneficiary 37 applied, does not refer to Beneficiary 37, and mentions "sales" not "claims." *Id.* ¶ 264.

The Government's allegations as to 111 sample beneficiaries, Compl. ¶¶ 791–98, similarly fail to allege a nexus between *any* of those beneficiaries and *any* supposed kickback. For instance, the Complaint alleges that Beneficiary "55" applied to enroll on "Dec. 16, 2015" "pursuant to the above-described kickbacks" from Aetna to eHealth, but the Complaint alleges "Aetna began paying kickbacks to eHealth" in "2016." *Id.* ¶¶ 387–88, 794. The Government cannot allege that claims were made over a multi-year, multi-defendant scheme and assume the nexus between claims and kickbacks must be lurking somewhere. *See U.S. ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 231 n.14 (1st Cir. 2004) (an FCA claimant cannot rely "upon the complexity of the edifice which he created").

Unable to link any AKS violation to a specific claim, the Government suggests *all* claims during the five-year "ongoing ... schemes" were false. Opp. 33; *see id.* 36. The notion that every beneficiary data submission was linked to kickbacks contradicts the Government's concessions that at least *some* marketing is permissible and each enrollee chose their plan independently. *See* 42 C.F.R. § 422.2260; Compl. ¶¶ 54, 58.⁷ At minimum, that sinks the idea that "*all* claims ... during this period" were invalid, adding urgency to the duty to "show that some *subset* ... was rendered false." *U.S. ex rel. Ge v. Takeda Pharm. Co.*, 737 F.3d 116, 124 (1st Cir. 2013).8

The Government insists it is enough to submit "sample claims" if a "complaint has sufficiently pleaded factual allegations about the underlying illegal schemes," Opp. 39, suggesting it need not bother tying claims to the scheme. But the Government cites nothing for this lax standard—a standard that conflicts with the Government's confessed need to allege "nexus." *Id.* 34. And the cases the Government does cite point the other way. In *Nargol*, the First Circuit recognized that, without showing that "*every* claim for payment was by definition fraudulent," one cannot get away with "offer[ing] no transactional particulars" and asserting "all sales were fraudulent." *U.S. ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29, 42 (1st Cir. 2017). And in *Duxbury*, the First Circuit applied the "more flexible standard" for cases in which a defendant "induce[s] *third parties*" to file claims (irrelevant here). *U.S. ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 29–31 (1st Cir. 2009) (emphasis in original). Even on that

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⁷ Moreover, the Complaint accuses Defendants of "steering" *50 times*, but CMS's long-held position is that lawful "[m]arketing *is* the act of steering ... a potential enrollee towards a plan or limited number of plans." CMS, *2017 Medicare Marketing Guidelines* 110 (June 10, 2016), https://perma.cc/59PG-YNPS; accord CMS, *2016 Medicare Marketing Guidelines* 111 (July 2, 2015), https://perma.cc/V5GS-RPZY; CMS, *2018 Medicare Marketing Guidelines* 101 (July 20, 2017), https://perma.cc/8DCN-YV9Q; CMS, *2019 Medicare Marketing Guidelines* 2 (Feb. 9, 2022), https://perma.cc/8N8R-WXM9.

⁸ Elsewhere, the Government frames its case as alleging the TPMOs "enrolled more beneficiaries ... than they otherwise would have but for the kickbacks," Opp. 28, which presupposes that many claims were lawfully submitted and, instead, theorizes there was an unspecified differential consisting of kickback-tainted claims.

lower standard, the allegations did what the Government has not done here: traced how payments in specific amounts on specific days tainted specific claims. *Id.* The same goes for *Regeneron*, where the Government "identifie[d] eleven claimants who allegedly received illegal copay subsidies" and then filed "claims for the remainder of the [drug] price." *United States v. Regeneron Pharms. Inc.*, 2025 WL 2207299, at *4 (D. Mass. Aug. 4, 2025). Again, the Government has not alleged that *any* exemplar enrollee was exposed to a kickback or kickback-influenced conduct.

Last, the Government cannot distinguish *Flanagan*. The Government here includes charts of beneficiary enrollments (not claims), states that "[f]or each of the ... beneficiaries" listed, the MAO "submitted claims," Compl. ¶¶ 791–98, and seems to say that *all* of these claims were false, Opp. 36. Likewise, the *Flanagan* complaint included charts of patients and treatments on whose behalf the facility sought reimbursement and alleged that "each of the ... claims" was false because "all of these treatments were tainted by kickbacks." *U.S. ex rel. Flanagan v. Fresenius Med. Care Holdings, Inc.*, 21-cv-11627, Dkt. 2-4, Compl. ¶ 273 (D. Mass. Oct. 5, 2021). The *Flanagan* complaint was dismissed for failing to tie the alleged scheme to specific claims and the Complaint here should be dismissed for the same reason. *U.S. ex rel. Flanagan v. Fresenius Med. Care Holdings, Inc.*, 142 F.4th 25, 37 (1st Cir. 2025).9

2. Count I: The Government Fails to Plead But-For Causation.

The Government agrees that, for Count I, it must plead that an "AKS violation was a butfor cause of the false claim." *Regeneron*, 128 F.4th at 328; *see* Opp. 26. It agrees this requires pleading that the claim "would not have occurred" but for a kickback. *Regeneron*, 128 F.4th at

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⁹ The Government has no good answer to Defendants' remaining cases. Opp. 39. For example, the Government tries to distinguish *U.S. ex rel. Senters v. Quest Diagnostics, Inc.* on the grounds that the "deficiency there was the relator's blanket allegation with no particular facts to show why the service for patient Y was not medically necessary," Opp. 39. But there, as here, the issue was that the complaint did not plead falsity because there were no allegations to show how a certification was untrue. Here: The deficiency is the absence of any particular facts to show why exemplar beneficiaries 1–111 were not "validly enrolled."

329; see Opp. 28. And the Government offers no causation defense for the "Examples of False Claims," Compl. ¶¶ 791–98, featured in its Complaint, see Mot. 36. It does not argue that even one of them involved a beneficiary who would not have enrolled absent an alleged kickback. Instead, the Government says it need not allege anything about the "decision-making" of "beneficiaries." Opp. 27. But the "heartland" of the AKS is to stop payments that "influence decisions on the provision of health care." Guilfoile, 913 F.3d at 192–93. The Government's inability to identify any specific claim that resulted from an alleged kickback is fatal to Count I. See U.S. ex rel. Martin v. Hathaway, 63 F.4th 1043, 1053 (6th Cir. 2023) (dismissing AKS "resulting from" theory where "[t]here's not one claim for reimbursement identified with particularity in this case that would not have occurred anyway").

The Government instead uses vague suppositions about aggregate market dynamics, Opp. 27–28, which flunk the above requirements and also fail on their own terms. The Government asserts kickbacks must have resulted in enrollments because enrollments for various MAO-TPMO combinations were "higher than its share of sales nationally." *Id.* 30; *see id.* 28. This conclusion is just a "generalized allegation[] that the scheme must have ... resulted in false claims," which is insufficient. *Flanagan*, 2022 WL 17417577, at *1 (D. Mass. Dec. 5, 2022). The Government's speculative inference also ignores its own allegations about the myriad individual factors that go into each enrollment decision: (1) each enrollment is a personal decision; (2) many beneficiaries enroll online without interacting with Defendants' marketing; and (3) even beneficiaries who enrolled by phone could only be enrolled with "consent." Compl. ¶ 58; *see id.* ¶ 37 (*beneficiaries* must "elect" plan). Overall fluctuations in enrollments say nothing about whether any individual enrollment was the but-for *result* of a kickback. *Cf. U.S. ex rel. Wilkerson v. Allergan Ltd.*, 782 F. Supp. 3d 658, 678 (N.D. Ill. 2025) ("[A]ssuming that every prescription written by a doctor who

received kickbacks resulted in the submission of a false claim would be overinclusive.").

Even if the Government's assumptions from aggregate allegations were otherwise viable, they fail to separate out aggregate enrollments attributable to alleged kickbacks from those attributable to admittedly lawful marketing. The Government argues only that there were "incremental" rises in enrollments that are attributable to increased *marketing* by Defendants more generally. Opp. 28–30. But it is undisputed that it is lawful for: (a) TPMOs to sell only some MA plans; (b) MAOs to pay TPMOs to influence beneficiaries' plan choices; (c) payments to be "based on" enrollment; and (d) MAOs to pay TPMOs commissions. *Supra* pp. 2–5, 7; Mot. 2. The Government's own theory of but-for causation, then, does not separate claims that "result[ed] from" lawful marketing from claims that "result[ed] from" activity the Government calls a kickback from claims that were made for reasons having nothing to do with the TPMOs at all.

II. THE GOVERNMENT FAILS TO PLEAD DISCRIMINATION-BASED FCA CLAIMS.

A. The Government Fails to Plead Particular False Claims.

The Government agrees its discrimination theory is that Defendants *prevented* people from enrolling in MA plans, which resulted in claims for payment *not* being submitted. Opp. 40. That is dispositive: "Because FCA liability attaches only to false *claims*, merely alleging facts related to a defendant's alleged *misconduct* is not enough." *Stonebrook*, 2024 WL 1142702, at *7 (emphasis in original); *see* Mot. 38–39. As the First Circuit has held, "even when a relator can prove that a defendant engaged in 'fraudulent conduct affecting the government,' FCA liability attaches only if that conduct resulted in the filing of a false claim for payment from the government." *U.S. ex rel. Booker v. Pfizer, Inc.*, 847 F.3d 52, 57 (1st Cir. 2017).

Unable to say that the misconduct it alleges resulted in the submission of any actual claim, the Government engages in sleight of hand. It says the "false claims" here are claims for payment Defendants made related to the individuals they enrolled in MA plans and, under the Government's

own theory, did *not* discriminate against. Opp. 48. That is insufficient as a matter of law. The FCA's false certification theory considers whether "the underlying transaction that gave rise to the claim" violated the relevant legal provision. *Regeneron*, 128 F.4th at 332–33. The Government, by contrast, seeks to sue where the "claims" it identifies do *not* arise from the alleged regulatory violation, relieving itself from its burden of identifying the specific claims that resulted from the alleged violation. *See Ge*, 737 F.3d at 124 (a complaint must "establish that false claims were submitted for government payment as a result of the defendant's alleged misconduct . . . merely alleging facts related to a defendant's alleged *misconduct* is not enough" (emphasis in original)). This would allow the Government to treble damages for claims where Defendants' actions did not violate any law, which is not permitted. *See U.S. ex rel. Glass v. Medtronic, Inc.*, 957 F.2d 605, 608 (8th Cir. 1992) (affirming grant of summary judgment because defendant's actions were "proper" under the applicable Medicare provision and therefore "not false or fraudulent").

The Government's opposition asserts a "fraudulent inducement" theory that it never pled. Opp. 50. The Complaint alleges that Defendants submitted "claims" that were false, not fraudulently induced. *See* Compl. ¶¶ 799–852. The Government "cannot amend its Complaint by assertions made in briefs." *Wood v. City of Haverhill*, 2024 WL 4189932, at *12 (D. Mass. Sept. 13, 2024). But even if the Government could shift to a new theory in its brief, its argument fails.

FCA fraudulent inducement claims stand on shaky ground. They proceed "without proof that" any "claims were fraudulent in themselves," *U.S. ex rel. Bettis v. Odebrecht Contractors of Cal., Inc.*, 393 F.3d 1321, 1323 (D.C. Cir. 2005), even though the current text of the FCA imposes liability only for a "claim," "record," or "statement" that is "false or fraudulent" in some way, 31 U.S.C. §§ 3729(a)(1)(A), (a)(1)(B); see U.S. ex rel. Cimino v. Int'l Bus. Machs. Corp., 3 F.4th 412, 424–27 (D.C. Cir. 2021) (Rao, J., concurring) (FCA "text ... does not readily suggest liability for

fraudulent inducement"). Fraudulent inducement claims are based, if anywhere, on a Supreme Court decision from 1943 that relied on legislative purpose, made no mention of "fraudulent inducement," and involved actual claims for payment with supposedly false prices. *Cimino*, 3 F.4th at 425 (citing *U.S. ex rel. Marcus v. Hess*, 317 U.S. 537 (1943)). Because fraudulent inducement claims often are used to stretch the FCA past its breaking point, courts often dispose of them on other grounds. *See D'Agostino v. ev3, Inc.*, 845 F.3d 1, 7–10 (1st Cir. 2016).

Even if the claim exists, however, its application here would be absurd. The Government would seek the return of every single dollar it paid three major insurers—"billions," in the Government's words, Opp. 40—akin to excluding them from Medicare Advantage retroactively. It would do this even though the discrimination it alleges did not result in any submitted claims, and based on allegations that Defendants should have covered *even more people* and thereby received *even more money* from the Government. And it would seek this *de facto* exclusion even though CMS—the agency that is empowered to exclude participants from Medicare—has never made any effort to do so based on any similar allegations. *See D'Agostino*, 845 F.3d at 8 (affirming dismissal of fraudulent-inducement theory where relevant agency did nothing to revoke drug approval despite allegation that approval had been fraudulently induced).

B. The Government Fails to Plead Falsity.

The Government rested its discrimination-based FCA claims on two regulations: 45 C.F.R. Part 92 and 42 C.F.R. § 422.110. Mot. 40. Now, in its opposition, the Government refers to a regulation that does not appear in its Complaint, 45 C.F.R. § 84.68; again, the Government "cannot amend its Complaint by assertions made in briefs," *Wood*, 2024 WL 4189932, at *12. In any event, the Government does not argue that § 84.68 applies any different legal framework.

The Government does not dispute, Opp. 40–45, that Part 92 incorporates the legal analysis applicable to claims under Section 504 of the Rehabilitation Act or that any claim under 42 C.F.R.

§ 422.110 would rise and fall for the same reasons. Nor does it contest Defendants' argument that the Government did not allege the existence of any particular disabled individual, much less facts about any adverse event suffered by such a person by reason of a disability. *See* Opp. 41. Instead, the Government insists it need not make any specific allegation about any individual who actually faced discrimination and the Court instead should "infer[]" the "existence of victims" from its allegations of "a substantial statistical decrease and from the specific alleged actions taken to cause that decrease." *Id.* 44. But such "mere conjecture ... is not a substitute for well-pleaded facts." *Quinones v. Frequency Therapeutics, Inc.*, 665 F. Supp. 3d 156, 179 (D. Mass. 2023), *aff'd*, 106 F.4th 177 (1st Cir. 2024). Rule 9(b) demands more. *D'Agostino*, 845 F.3d at 10 (Rule 9(b) requires "alleging with particularity examples of actual *false* claims"). And even the Government's own authorities (Opp. 44) illustrate its failure to meet this requirement.

C. The Government Fails to Plead That Any Violation Was Material.

The Government does not dispute the law applicable to the materiality element of its discrimination-based claim. *See* Mot. 26, 42–43; *supra* pp. 9–12. The Government also admits it seeks to establish materiality solely by reference to three factors discussed by the Supreme Court in *Escobar*. Opp. 44. As Defendants argued, the Government fails all three. Mot. 42–45.

First, the Government does not dispute that it makes no allegation "about prior government

¹⁰ That conjecture is particularly inappropriate given the many other factors that could explain the alleged fluctuation in the proportion of Defendants' enrollees. For one, there are fluctuations in the overall number of disabled individuals who are eligible for Medicare from one year to the next. *See* Centers for Medicare & Medicaid Servs., CMS Program Statistics – Medicare Total Enrollment, available at https://perma.cc/DYP6-KYRJ (indicating a consistent decrease in disabled individuals and individuals under the age of 65 who enrolled in Medicare each year from 2018 through 2023). For another, there have been an increasing number of health plans designed specifically for such individuals—so-called dual-eligible special-needs plans that cater to individuals who are both Medicaid and Medicare eligible.

¹¹ Cook v. Dept. of Mental Health, 10 F.3d 17, 23 (1st Cir. 1993) (permitting plaintiff to proceed on "perceived disability" theory due to evidence as to plaintiff's circumstances); Greene v. City of New York, 773 F. Supp. 3d 94, 108–09 (S.D.N.Y 2025) (similar); Guckenberger v. Boston Univ., 974 F. Supp. 106, 136 (D. Mass. 1997) (rejecting class action's "screening out" theory even with plaintiff-specific evidence); Doukas v. Metro. Life Ins. Co, 950 F. Supp. 422 (D. N.H. 1996) (allowing similar theory based on plaintiff-specific evidence).

decisions to refuse payment when faced with similar purported violations." *Id.* 42. It also does not dispute that it cannot do so because its theory is about violations that result in claims *not* being submitted. *See id.* The Government thus cannot allege that it "consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement." *Escobar*, 579 U.S. at 195. This Court has dismissed FCA claims for that reason. *E.g.*, *Stonebrook*, 2024 WL 1142702, at *10; *U.S. ex rel. Allen v. Alere Home Monitoring, Inc.*, 334 F. Supp. 3d 349, 366 (D. Mass, 2018). 12

The Government defends its pleading failure by claiming it "did not have 'actual knowledge'" of Defendants' alleged violations "when entering [MA] contracts ... or when paying claims under these contracts." Opp. 45–46. But that has nothing to do with the Government's burden of pleading that it refuses to pay claims (by anyone) "based on noncompliance with the particular statutory, regulatory, or contractual requirement." *Escobar*, 579 U.S. at 195. Absent any allegation that this has happened, the Government is simply asking the Court to turn the FCA into "an all-purpose antifraud statute or a vehicle for punishing ... contract or regulatory violations." *U.S. ex rel. Escobar v. Universal Health Servs.*, 842 F.3d 103, 110 (1st Cir. 2016).

That result would be particularly inapt here. The Government admits that CMS has "other regulatory tools" (Opp. 46) to address such allegations, including administrative sanctions and monetary penalties it can apply to practices that "have the effect of denying or discouraging enrollment," 42 C.F.R. § 422.752(a)(4), yet it did not use them against Defendants (or anyone else), *see*, *e.g.*, *Hawaii ex rel. Torricer v. Liberty Dialysis-Hawaii LLC*, 512 F. Supp. 3d 1096, 1116–17 (D. Haw. 2021) (lack of pursuit of "alternative sanctions" weighs against materiality).

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¹² The Government does not dispute that it cannot make up for this failure with either (1) "[a]llegations about what Defendants said or did" or (2) ad nauseum recitations of the word "material." Mot. 42–45.

Second, the Government does not dispute that a regulatory violation is immaterial unless it "go[es] to the 'essence of the bargain' between Defendants and CMS," which requires an examination of the "core purpose" of Defendants' services. See Opp. 46–47. Here, the Government paid for insurance coverage and it received—and was accurately billed for—precisely that. The Government does not dispute that Defendants provided appropriate coverage to their enrollees. Id. 43–44. The regulatory violations the Government alleges are ancillary to all of that—and, if the Government is to be believed, would have led to more payments for coverage—regardless of whether they affected a "small slice" of the population or a larger one. Id. 47–48. Nor can the Government convert these ancillary regulations into a separate "core" purpose of the MA program simply because an agency chose to regulate on the topic, id. 46, as such a rule would impermissibly make every regulatory violation material, see Escobar III, 842 F.3d at 110–11.

Third, the Government argues that compliance with the regulations is a "condition of payment." Opp. 45.¹³ But it cannot identify anywhere in either provision in its Complaint—42 C.F.R. § 422.110 or 45 C.F.R. § 92.101(a)—with "express and absolute language stating that payment is conditioned on compliance with the regulation." *Escobar III*, 842 F.3d at 111.

The Government argues that those regulations are also included in contracts between MAOs and CMS. Opp. 45. It points to a different regulation requiring such contracts to reference "all the applicable requirements and conditions set forth in this part and in general instructions." 42 C.F.R. § 422.504(a). Incorporating a regulation in a contract, however, does not make the regulation an express condition of payment absent a showing "that the government expressly identified [the requirement] as a condition of payment." *U.S. ex rel. Bonzani v. United Techs. Corp.*, 662 F. Supp. 3d 217, 229 (D. Conn. 2023). Otherwise, entire swaths of the Code of Federal

 13 A regulation being a condition of payment is insufficient to make it "material." *Escobar*, 579 U.S. at 191.

Regulations would become conditions of payment. *See Escobar*, 579 U.S. at 196. That is why a court has already rejected the Government's argument that § 422.504(a)'s required contract terms transform other regulations into conditions of payment. *See U.S. ex rel. Nedza v. Am. Imaging Mgmt., Inc.*, 2019 WL 1426013, at *7 (N.D. Ill. Mar. 29, 2019).

D. The Government Fails to Plead Any Violation Caused a False Claim.

The Government does not dispute that it failed to plead that the alleged violations of non-discrimination laws caused any claim to be submitted or any loss. Mot. 45. The Government's sole counter is that causation is not an element, but it does not address Defendants' statutory argument as to why causation *is* an element. *Id.* at 45–46 & n.15. Instead, it implies the First Circuit foreclosed the argument, citing one case with a "cf." signal. That case, *Regeneron*, discussed a false-certification claim based on alleged AKS violations. 128 F.4th at 334. And months later, the First Circuit emphasized that even for AKS-based claims, it still requires a "connection between false records and/or statements and the intent to have a false claim paid for by the government programs." *Flanagan*, 142 F.4th at 37. Nor did *Regeneron* overturn the First Circuit's prior rulings on false certification: "FCA liability attaches only if" the regulation-violating conduct "resulted in the filing of a false claim for payment from the government." *Booker*, 847 F.3d at 57. The Government is simply wrong as a matter of law.

E. The Government Fails to Plead Damages.

The Government's damages argument fails for similar reasons. The Government admits that any damages must have been "sustained ... 'because of'" the alleged "misconduct," Opp. 50–51, and does not dispute that the First Circuit applies a simple benefit-of-the-bargain analysis, *see* Mot. 48.¹⁴ The Government's theory of liability results in no damages here because, absent the

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¹⁴ The Government muses that it might seek to recover all MA payments to Defendants. Opp. 51. But it never squares that theory with Defendants' cases, and the Government's own cases reject the concept. *See* Opp. 51; *U.S. ex rel. Feldman v. van Gorp*, 697 F.3d 78, 90 (2d Cir. 2012).

alleged conduct, Defendants would have submitted *more claims* and the Government would have paid *more money*. *See U.S. ex rel. Davis v. D.C.*, 679 F.3d 832, 839–40 (D.C. Cir. 2012) (upholding dismissal of damages remedy where allegations made clear "the government suffered no damages"). Nor does the Government dispute that the MA payments it made were for insurance coverage for individuals who were *not* affected by the alleged discrimination and who received exactly the coverage the Government paid for. Mot. 44, 48. The Government likewise ignores Defendants' argument that it cannot articulate a theory of a "quantifiable loss from" the supposed "non-enrollment of other individuals." *Id.* at 48 (emphasis in original). In fact, it cites a case that found that "an accurate calculation" of a damages-from-non-enrollment theory is "nearly impossible" to do. Opp. 51 (quoting *U.S. ex rel. Tyson v. Amerigroup III., LLC*, 488 F. Supp. 2d 719, 732 (N.D. III. 2007)). ¹⁶

III. THE GOVERNMENT FAILS TO PLEAD CONSPIRACY CLAIMS.

Beyond failing to allege any underlying FCA violation, the Government does not reveal the conspiracy theory it is pursuing. It is impossible to tell if the Government envisions multiple bilateral conspiracies between select TPMOs and MAOs, or a hub-and-spoke conspiracy with all Defendants. The opposition does not clarify this and instead cites a scattershot mix of paragraphs and asks the Court to infer a conspiracy from the "cumulative effect" of parallel commercial relationships. Opp. 52. This approach does not satisfy Rule 9(b). *D'Agostino*, 845 F.3d at 10.

These deficiencies are not technicalities. They go to the core of a § 3729(a)(1)(C) claim: the Government must plead that at least two independent actors reached a "meeting of the minds"

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¹⁵ The Government's footnoted argument that it believes it can recover "statutory penalties," Opp. 51 n.8, attacks a straw man. Defendants challenge the Government's request for damages. Whether the Government, having suffered no damages, can obtain statutory penalties—and any attendant constitutional issues—is not yet at issue.

¹⁶ *Tyson* allowed recovery of such "nearly impossible" damages because the exclusion of individuals caused the government to pay more than it otherwise would have for the individuals the defendants did enroll. Here, accepting the Government's theory as true, its payments for those individuals were unchanged. Compl. ¶ 42.

to defraud the Government. *See U.S. ex rel. Est. of Cunningham v. Millennium Lab'ys of Cal.*, 2014 WL 309374, at *2 (D. Mass. Jan. 27, 2014). The Complaint does not allege that any TPMO agreed with any MAO to commit fraud. Referring to "dozens of paragraphs" is not a substitute for pleading an actual agreement. Opp. 52.

The Government's examples make this point. For example, the Complaint cites a communication between Aetna and SelectQuote regarding directing the "traffic" of disabled Medicare beneficiaries and also SelectQuote's alleged agreement to "keep a close eye on" the proportion of Humana enrollments. *Id.* at 53 (citing Compl. ¶¶ 333, 503). These statements do not establish that any Defendants agreed to take unlawful action or acted upon any alleged agreement, let alone agreed to violate the FCA. *See Millennium Lab'ys of Cal.*, 2014 WL 309374, at *2. At most, they reflect ordinary communications between counterparties. *See id*.

The Government's attempt to ground its conspiracy claim in alleged agreements between Aetna entities (Opp. 53) is simply an attempt to allege an intracorporate conspiracy, which is not a viable theory under the FCA. See Commonwealth ex rel. Martino-Fleming v. S. Bay Mental Health Ctr., Inc., 334 F. Supp. 3d 394, 402–03 (D. Mass. 2018). In attempting to distinguish Defendants' cases, the Government highlights a fatal flaw in its own theory. The opposition quotes Angelo for the proposition that "a contractual relationship alone does not suggest collusion any more than it suggests a legitimate business relationship." Opp. 55 (quoting U.S. ex rel. Angelo v. Allstate Ins. Co., 106 F.4th 441, 453 (6th Cir. 2024)). But this is precisely what the Government relies on here: a series of parallel, bilateral contracts between MAOs and TPMOs codifying garden variety commercial relationships consistent with CMS guidance, not a conspiracy. Because the Complaint fails to plead FCA conspiracy with particularity, Counts VI and VII must be dismissed.

IV. THE GOVERNMENT FAILS TO PLEAD AN UNJUST ENRICHMENT CLAIM.

The Government argues its unjust enrichment claims can proceed despite an "adequate

remedy at law," Opp. 56–57, but ignores numerous decisions from this District "routinely" saying the opposite, *e.g.*, *United States v. Regeneron Pharms. Inc.*, 2023 WL 6296393, at *14 (D. Mass. Sept. 27, 2023). The Government also does not dispute that express contracts govern the subjects in dispute, Mot. 51, which precludes any unjust-enrichment theory, *see Philibotte v. Nisource Corp. Servs. Co.*, 793 F.3d 159, 167 (1st Cir. 2015).

The Government asks the Court to exempt it from these rules because it might be "left without a remedy" if it cannot prove its FCA claim. Opp. 57. But it is the "availability of a remedy at law, not the viability ... that prohibits a claim for unjust enrichment." *Regeneron*, 2023 WL 6296393, at *14. 'We might lose' is not a basis for "law-making by federal courts." *Am. Elec. Power Co. v. Connecticut*, 564 U.S. 410, 423 (2011). 17

Finally, the Government ignores—and thereby concedes—Defendants' argument, Mot. 52, that the Court should, at minimum, strike the jury demand on the unjust enrichment claims.

V. LEAVE TO AMEND SHOULD BE DENIED.

Leave to amend should be denied. The Government's one-sentence request says nothing about how the Government—after a three-year investigation—would amend to rescue its case. *See*, *e.g.*, *StandWithUs Ctr. v. Mass. Inst. of Tech.*, 158 F.4th 1, 26–27 (1st Cir. 2025).

CONCLUSION

The Court should dismiss the Complaint, in its entirety, with prejudice.

Dated: December 19, 2025 Respectfully submitted,

¹⁷ The Government's claim that "courts often permit the United States to seek unjust enrichment damages as a 'back-up' in FCA cases" is belied by its lack of examples in the First Circuit in the last thirty years. Opp. 57–58. *United States v. Am. Heart Rsch. Found., Inc.* turned on claim preclusion and *res judicata*. 996 F.2d 7, 10–11 (1st Cir. 1993). And *United States v. Lahey Clinic Hosp., Inc.* asked whether 28 U.S.C. § 1345 displaced common law claims and did not address the FCA. 399 F.3d 1, 4 (1st Cir. 2005).

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing document was served upon all counsel of record via ECF on December 19, 2025.

/s/ Zachary R. Hafer Zachary R. Hafer Dated: December 19, 2025