UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

DEFENDANTS' JOINT MOTION TO DISMISS
THE GOVERNMENT'S COMPLAINT IN PARTIAL INTERVENTION

Defendants eHealth Inc. and eHealthInsurance Services, Inc. (together "eHealth"); CVS Health Corporation; Aetna Life Insurance Company; Aetna Inc.; Humana Inc.; Elevance Health, Inc.; GoHealth, Inc. ("GoHealth"); and SelectQuote, Inc. ("SelectQuote") jointly move, pursuant to Fed. R. Civ. P. 12(b)(6), 8(a), and 9(b), to dismiss all counts of the Government's Complaint in Partial Intervention (ECF No. 41) (the "Complaint"), with prejudice. As grounds for this motion, Defendants rely on three memoranda of law filed contemporaneously herewith:

1. The Memorandum of Law in Support of Defendants' Motion to Dismiss the Government's Complaint in Partial Intervention sets forth multiple, independent reasons for dismissal of all counts in the Complaint that apply to all Defendants named in the Complaint.[1]

2. The TPMO Defendants' Supplemental Memorandum of Law in Support of Motion to Dismiss the Government's Complaint in Partial Intervention sets forth

[1] If Count VIII of the Complaint (claiming unjust enrichment) were to survive dismissal, notwithstanding Defendants' arguments, the Court should at least strike the Government's demand for a jury trial as to that claim for reasons also set forth in this memorandum of law.

additional, independent grounds for dismissal of the Government's claims against eHealth, GoHealth, and SelectQuote.[2]

3. CVS Health Corporation and Aetna Inc.'s Supplemental Memorandum of Law in Support of Motion to Dismiss the Government's Complaint in Partial Intervention sets forth additional, independent grounds for dismissal of the Government's claims against CVS Health Corporation and Aetna Inc.

A proposed order accompanies this motion.

REQUEST FOR ORAL ARGUMENT

Defendants request oral argument on this Motion. Defendants understand that the Court has scheduled oral argument for January 21, 2026.

Dated: August 19, 2025

Respectfully submitted,

/s/ Zachary R. Hafer
Zachary R. Hafer (BBO #569389)
Adam M. Katz (BBO #706834)
Isabel C. McGrath (BBO #712925)
SIMPSON THACHER & BARTLETT LLP
855 Boylston Street
Boston, MA 02116
Telephone: (617) 778-9200
zachary.hafer@stblaw.com
adam.katz@stblaw.com
isabel.mcgrath@stblaw.com
Counsel to eHealth, Inc. and eHealthInsurance Services, Inc.

/s/ Holly M. Conley
Enu Mainigi (*pro hac vice*)
Kenneth Brown (*pro hac vice* pending)
Holly M. Conley (*pro hac vice*)
Benjamin Hazelwood (*pro hac vice* pending)
Jeffrey G. Ho (BBO #714047)
WILLIAMS & CONNOLLY LLP
680 Maine Avenue SW
Washington, DC 20024
Telephone: (202) 434-5000
emainigi@wc.com
kbrown@wc.com
hconley@wc.com
bhazelwood@wc.com
jho@wc.com
Counsel to CVS Health Corporation, Aetna Life Insurance Company, and Aetna Inc.

[2] TPMO stands for "third-party marketing organization," as defined at 42 C.F.R. § 422.2260. The TPMO Defendants in this case are eHealth, GoHealth, and SelectQuote.

/s/ Richard Westling
Richard Westling (*pro hac vice*)
PROSKAUER ROSE, LP
1001 Pennsylvania Ave., NW, Suite 600 South
Washington, DC 20004
Telephone: (202) 416-5876
rwestling@proskauer.com
Counsel to SelectQuote, Inc.

/s/ Erik W. Weibust
Erik W. Weibust (BBO #663270)
Clay Lee (*pro hac vice*)
EPSTEIN BECKER & GREEN PC
One Financial Center, Suite 1520
Boston, MA 02111
Telephone: (617) 603-1090
eweibust@ebglaw.com
clee@ebglaw.com
Counsel to SelectQuote, Inc.

/s/ Kelly H. Hibbert
Kelly H. Hibbert (*pro hac vice*)
Michael Shaheen (*pro hac vice*)
Troy Barsky (*pro hac vice*)
Payal Nanavati (*pro hac vice*)
Lauren J.R. Nunez (BBO #687390)
CROWELL & MORING LLP
1001 Pennsylvania Ave., NW
Washington, DC 20004
Telephone: (202) 624-2500
khibbert@crowell.com
mshaheen@crowell.com
tbarsky@crowell.com
pnanavati@crowell.com
lnunez@crowell.com
Counsel to Humana Inc.

/s/ Laura McLane
Laura McLane (BBO #644573)
David Gacioch (BBO #660784)
Mara Theophila (BBO #704763)
Natasha Dobrott (BBO #705287)
MCDERMOTT WILL & SCHULTE LLP
200 Clarendon Street, 58th Floor
Boston, MA 02116
Telephone: (617) 535-4410
lmclane@mwe.com
dgacioch@mwe.com
mtheophila@mwe.com
ndobrott@mwe.com
Counsel to GoHealth, Inc.

/s/ Lisa M. Noller
Lisa M. Noller (*pro hac vice*)
Patrick J. McMahon (*pro hac vice*)
Jamie Steven (BBO #705904)
FOLEY & LARDNER LLP
321 North Clark Street, Suite 3000
Chicago, Illinois 60654
Telephone: (312) 832-4500
lnoller@foley.com
pmcmahon@foley.com
Counsel to Elevance Health, Inc.

CERTIFICATE OF COMPLIANCE WITH LOCAL RULE 7.1

Pursuant to Local Rule 7.1(a)(2), I hereby certify that counsel for Defendants conferred in good faith with counsel for the Government regarding the foregoing motion in an effort to resolve or narrow the issues contained therein.

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

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 August 19, 2025.

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

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA *ex rel.* ANDREW SHEA, *Plaintiff,* v. eHEALTH, Inc., *et al.*, *Defendants.*	Civil Action No. 21-cv-11777-DJC

[PROPOSED] ORDER

Upon the Joint Motion to Dismiss the Government's Complaint in Partial Intervention filed by Defendants eHealth Inc. and eHealthInsurance Services, Inc.; GoHealth, Inc.; SelectQuote, Inc.; Humana Inc.; CVS Health Corporation; Aetna Life Insurance Company; Aetna Inc.; and Elevance Health, Inc. (together, "Defendants"), having carefully considered the parties written submissions and oral argument, the Court hereby GRANTS Defendants' Joint Motion and ORDERS that all claims asserted in the Complaint in Partial Intervention (ECF No. 41) are hereby DISMISSED WITH PREJUDICE. Judgment shall enter in Defendants' favor on all such claims.

Dated: _____

_____
DENISE J. CASPER
CHIEF UNITED STATES DISTRICT JUDGE

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE GOVERNMENT'S COMPLAINT IN PARTIAL INTERVENTION

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INTRODUCTION

This case is a classic attempt at regulation by litigation. Hoping to reshape the Medicare Advantage ("MA") industry, the Government levels novel False Claims Act ("FCA") allegations against a vast swath of the MA market. The Government's principal claim relates to payments for MA marketing services—authorized by statute and ***long allowed and regulated*** by the Centers for Medicare & Medicaid Services ("CMS")—and retroactively insists that these industry-standard payments are illegal kickbacks under the Anti-Kickback Statute ("AKS"). The Government's secondary claim is no better: alleging that the MA industry "discriminated" against beneficiaries in violation of the FCA, despite the Government's theory that the "scheme" ***prevented*** claims for payment from being submitted, and despite the Government's failure to identify ***anyone*** who faced discrimination. Neither claim is viable. This case should be dismissed with prejudice.

Medicare is a healthcare program for the elderly and people with disabilities, administered by CMS. Medicare Advantage is an alternative to traditional "fee for service" Medicare (in which CMS pays healthcare providers directly). Under the MA program, eligible beneficiaries can enroll in MA plans offered by private insurers known as Medicare Advantage Organizations ("MAOs"), such as Defendants Aetna Life Insurance Company ("Aetna"), Humana Inc. ("Humana"), and Elevance Health, Inc. ("Elevance Health"). CMS pays MAOs "capitated" (per enrollee) fixed monthly rates; in exchange for these capitated payments, the MAOs take on the risk of insuring each enrollee's medical care irrespective of the services that each enrollee receives. MAOs then pay healthcare providers for the medical services provided to beneficiaries.

For over 25 years, MAOs have lawfully and routinely paid third parties—*e.g.*, agents, brokers, and Third-Party Marketing Organizations ("TPMOs") like Defendants eHealth, Inc. and eHealthInsurance Services, Inc. ("eHealth"), GoHealth, Inc. ("GoHealth"), and SelectQuote, Inc. ("SelectQuote")—to help beneficiaries enroll and to provide other administrative services such as

marketing. Marketing is meant to influence consumers and MA marketing is no different. In fact, CMS rules *define* lawful "Marketing" to include "Influenc[ing] a beneficiary's decision-making process." 42 C.F.R. § 422.2260. CMS merely requires that marketing payments not exceed the "value of those services in the marketplace"—*i.e.*, "fair-market value" for the marketing services. *Id.* § 422.2274(e) (version effective Mar. 22, 2021); *id.* § 422.2274(b)(1)(iv)(B) (version effective June 15, 2018) (requiring "fair-market value"); *id.* § 422.2274(b)(1)(iii)(B) (version effective Mar. 16, 2015) (same). The Government here does not deny that marketing services were provided.

It is plain from the Complaint that the Government disapproves of CMS's longstanding payment framework. This case is thus less a challenge under that years-old framework than it is an attempt to retroactively implement by litigation a very different regime that has never gone into effect, and which CMS proposed (unsuccessfully) years after the events alleged here. In 2024, CMS tried to ***prospectively*** change its regulations on marketing payments to subject the payments to new rules starting in 2025. But a court enjoined CMS from doing so because those new regulations would have cavalierly upended the agency's prior approach. Silent on this history, the Government now contends that marketing payments under CMS's decades-old marketing-payments regime were illegal kickbacks all along and pursues a theory—one that aligns with the regulatory change that CMS recently tried and failed to implement—claiming that six leading participants in the MA market violated the AKS. The Government also asks this Court to endorse the novel and erroneous theory that it can use the FCA to police alleged discrimination where the entire theory rests on the assumption that the alleged "discrimination" caused claims ***not*** to be submitted, and there are no allegations of any specific beneficiary facing discrimination.

The Complaint succeeds in flooding the Court with hundreds of hand-picked, selectively excerpted, and acontextual emails and communications. But it fails to convert the insinuation of

wrongdoing into plausible violations of the FCA, AKS, or anti-discrimination laws. For a host of independent and incurable reasons, the Complaint must be dismissed.

First, the Complaint fails to assert FCA claims based on alleged AKS violations (Counts I, II, IV). To start, the Government has not alleged a predicate AKS violation. Payments authorized and regulated by Congress and CMS cannot be illegal kickbacks. Although that basic flaw is dispositive, the Government also fails to plead an AKS violation because it does not allege that any Defendant induced the purchase of a "good," "item," "service," or "facility" within the meaning of the AKS. Nor can the Government plead any unlawful remuneration under the AKS because it does not allege that any payment exceeded fair market value for the legitimate services provided in return or explain how the marketing payments here differed from marketing payments courts have found permissible under the AKS. Even if the Government could articulate an AKS violation (it cannot), it fails to plead the elements of an FCA claim based on AKS violations. The Government does not plausibly allege "false certification" FCA claims (Counts II, IV) because it cannot allege that any violations were material to CMS's payment decisions and does not connect any false claim to the supposed kickback scheme. And the Government's "resulting from" FCA claim (Count I) fails to plead facts that, if proved, would show that any "illegal" marketing payments were the "but for" cause of any alleged false claims.

Second, the Complaint fails to assert FCA claims based on alleged discrimination (Counts III, V). The Government's theory is that Defendants designed marketing campaigns to discourage the enrollment of beneficiaries made eligible for Medicare by disability (as opposed to age). But the Government fails to identify any false claim that related to this purported discrimination. Nor can it. The FCA imposes liability for the ***submission*** of claims for payment, but the Government's entire theory is that Defendants ***stopped*** claims for payment from being submitted by preventing

beneficiaries from enrolling in their MA plans. Besides this fundamental defect, the Government also fails to plead that any anti-discrimination law was violated, that the Government would have found a violation thereof "material," or that any alleged false certifications caused any loss.

Third, the Government's tack-on claims for FCA conspiracy (Counts VI, VII) and unjust enrichment (Count VIII) fail for many of the same reasons and for others still. Among other things: the Government does not even specify whether it alleges one conspiracy involving all Defendants or several cross-cutting smaller ones, and it cannot bring an unjust enrichment claim because there is no federal common law to backstop this claim and there is also an adequate remedy at law.

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

BACKGROUND[1]

A. Medicare Advantage

Medicare is a federally funded health insurance program. *See* 42 U.S.C. §§ 1395c *et seq*. To be eligible for Medicare, a person must be over age 65, be disabled, or have end-stage renal disease. *See* 42 C.F.R. §§ 406.20, 407.10, 422.50. Medicare Parts A and B are fee-for-service, which means they involve payments directly from CMS to medical providers for inpatient and outpatient care. *See* 42 U.S.C. §§ 1395c–1395i-6 (Part A); *id*. §§ 1395j–1395w-6 (Part B).

Medicare Part C is the MA program. MA "is a private alternative to traditional Medicare in which the government contracts with private health insurers to provide beneficiaries with the coverage they otherwise would receive under traditional Medicare." *Americans for Beneficiary Choice v. United States Dep't of Health & Hum. Servs.*, 2024 WL 3297527, at *1 (N.D. Tex. July 3, 2024) ("*AFBC*") (citing 42 U.S.C. § 1395w-22(a)); *see also* ECF No. 41 ("Compl.") ¶ 37. The private insurers that participate are known as MAOs. Defendants Aetna, Humana, and Elevance

[1] Defendants treat the Complaint's factual allegations as true for purposes of this motion to dismiss only.

Health are MAOs (together, "MAO Defendants"). MAOs are responsible for managing the care of enrolled beneficiaries, including contracting with health care providers to provide health care services to those beneficiaries. *See* 42 C.F.R. §§ 422.200 *et seq.* MAOs must generally offer at least the same benefits as Parts A and B, but MAOs also offer additional benefits such as dental, hearing, and vision coverage. *See* 42 U.S.C. § 1395w-22(a); 42 C.F.R. § 422.100.

"'Unlike traditional Medicare, CMS does not pay for every service provided through [MA]. Rather, it pays [MAOs] a set, monthly payment regardless of the number of' services the enrollee uses or the plan provides." *Holt v. Medicare Medicaid Advisors, Inc.*, 2022 WL 3587358, at *2 (W.D. Mo. Aug. 22, 2022), *aff'd*, 115 F.4th 908 (8th Cir. 2024) (quoting *United States ex rel. Gray v. UnitedHealthcare Ins. Co.*, 2018 WL 2933674, at *2 (N.D. Ill. June 12, 2018)); *see* Compl. ¶ 43. These fixed payments are sometimes referred to as "capitated" payments. To obtain these capitated payments, MAOs make periodic submissions of enrollment and other data to CMS and make various certifications in those submissions. Compl. ¶¶ 775–76. Here, the Government seems to allege that these submissions were the "false claims." *Id.* ¶ 781.

Because there are numerous MA plans available to most Medicare beneficiaries (based on, and depending on, where they live), insurers have long relied on agents, brokers, and TPMOs to market MA plans, help beneficiaries enroll, and provide other administrative services. *See id.* ¶¶ 52–53. Such third parties include Defendants eHealth, GoHealth, and SelectQuote (together, "TPMO Defendants"). Some agents and brokers are "employed" by one MAO or plan, while others are "independent" (*i.e.*, not employed by and captive to a single MAO). 42 C.F.R. § 422.2274 (version effective Sept. 18, 2008); *Revisions to the Medicare Advantage and*

Prescription Drug Benefit Programs, 73 Fed. Reg. 54,226, 54,250 (Sept. 18, 2008).[2] As CMS has long acknowledged, few—if any—agents or brokers represent all MAOs or plans that are available to a given beneficiary. *See id.* at 54,237; Compl. ¶ 53 ("Independent insurance brokers typically must be 'appointed' by a particular MAO to sell plans from that MAO."); *AFBC*, ECF No. 54, Gov't Br. in Support of Mot. for Summary Judgment at 17 (N.D. Tex. Nov. 8, 2024) ("[A] plan need not only contract with agents who represent 'all possible competitors in a market.'").[3]

B. Since 2008, CMS Has Regulated MAO Payments to Third Parties.

In 2008, Congress directed the Department of Health and Human Services ("HHS") to "establish limitations" with respect to certain MA sales and marketing activities, including limits for "[t]he use of compensation other than as provided under guidelines established by the Secretary" concerning agents, brokers, and other third parties. 42 U.S.C. § 1395w-21(j)(2)(D); *see AFBC*, 2024 WL 3297527, at *1. Congress required these guidelines to "ensure that the use of compensation ***creates incentives*** for agents and brokers to enroll individuals in the [MA] plan that is intended to best meet their health care needs." 42 U.S.C. § 1395w-21(j)(2)(D) (emphasis added); *see* Compl. ¶ 76; *AFBC*, 2024 WL 3297527, at *1.

Acting on this directive, CMS first issued 42 C.F.R. § 422.2274 in 2008. That regulation provided for two different types of payments from MAOs to third parties: (1) payments that were "compensation" to third parties "for the sale of a MA product" (*i.e.*, the specific service of helping

[2] While employed (*i.e.*, non-"independent") agents and brokers are paid to sell for only one MAO—and are thus financially incentivized to steer every beneficiary with whom they speak into that MAO's plans to the exclusion of all others—the Government here does not question the lawfulness of such arrangements.

[3] The Court can take judicial notice of the Government's filings in *AFBC*. *See Kowalski v. Gagne*, 914 F.2d 299, 305 (1st Cir. 1990). Indeed, the Court should treat the factual assertions the Government has made in its filings in *AFBC* as judicial admissions to which the Government is formally bound. *See, e.g.*, *Atlas Glass & Mirror, Inc. v. Tri-North Builders*, 997 F. 3d 367, 373 (1st Cir. 2021) ("Unlike ordinary admissions, which are admissible but can be rebutted by other evidence, judicial admissions are conclusive on the party making them.") (quoting *United States v. Belculfine*, 527 F.2d 941, 944 (1st Cir. 1975)).

a beneficiary enroll in a plan of his or her choice); and (2) payments for other (non-enrollment) services that were not "compensation." 42 C.F.R. § 422.2274(a)(1) (version effective Sept. 18, 2008); 73 Fed. Reg. at 54,250–51; *see* Compl. ¶¶ 77–79.

1. Compensation Payments

CMS's 2008 regulation defined "compensation" payments from MAOs to third parties to include all forms of variable compensation "relating to the sale or renewal of the policy," such as "commissions, bonuses, gifts, prizes, awards and finders fees." 42 C.F.R. § 422.2274(a)(1)(i) (version effective Sept. 18, 2008); *see also* 73 Fed. Reg. at 54,250–51; Compl. ¶ 77.[4] For these "compensation" payments, CMS set specific dollar caps on an annual basis. *See, e.g.*, 42 C.F.R. § 422.2274(a)(1)(i)–(ii) (version effective Nov. 14, 2008); 42 C.F.R. § 422.2274(a) (version effective Mar. 22, 2021); *see also* Compl. ¶ 77. CMS has long characterized these annual dollar caps as its determination of what constitutes fair market value for enrollment services. *See, e.g.*, *id.* § 422.2274(b)(1) (version effective Oct. 1, 2015); *id.* § 422.2274(a) (version effective Mar. 22, 2021). CMS also imposed financial penalties on third parties when individuals rapidly disenrolled from plans to incentivize those third parties to introduce beneficiaries to plans that well suited their individual needs—plans with which the beneficiaries were likely to be satisfied over the long term. *Id.* § 422.2274(a)(4) (version effective Sept. 18, 2008); 73 Fed. Reg. at 54,251. Conversely, if beneficiaries remained enrolled in plans, brokers stood to earn more. 42 C.F.R. § 422.2274(a)(4) (version effective Sept. 18, 2008); 73 Fed. Reg. at 54,251. In short, CMS promulgated financial incentives for well-fitting plans as Congress directed.

[4] In another example of how the Government here simply attacks CMS's longstanding system—with which Defendants complied—the Complaint repeatedly frames "contests" featuring "cash awards," "gift cards," and other "prize giveaways" as somehow nefarious, *see, e.g.*, Compl. ¶¶ 150, 582, 626–39, 646, 658–69, 693–94, 740–41, when CMS's regulations quoted here expressly contemplated such incentive structures as part of how MAOs were allowed to compensate agents, brokers, and TPMOs.

"Compensation" payments for enrollment services are not at issue in this case.

2. Non-Compensation Payments: Administrative Payments

At issue here is another type of third-party payment that CMS authorized but structured differently from the capped enrollment "compensation" payments described above. Specifically, CMS's 2008 regulation—and its regulations since—recognized that MAOs also could make payments to third parties for *non*-"compensation" payments: payments for services ***other than*** enrolling a beneficiary or selling a plan. These are often called administrative payments and include marketing payments. *See, e.g.*, *AFBC*, 2024 WL 3297527, at *1 ("These [administrative] services include . . . ***launching marketing campaigns***.") (emphasis added).

Unlike with "compensation," CMS's regulations did not impose a specific dollar limit on this category of marketing and other administrative services. Instead, CMS—throughout the entire period at issue in this case—required payments for such services to be consistent with fair market value, without otherwise taking a position on any particular number or imposing a cap. *See* 42 C.F.R. § 422.2274(a)(1)(iv) (version effective Nov. 14, 2008) (requiring "fair-market value"); *id.* (version effective June 6, 2011) (same); *id.* § 422.2274(a)(1)(iv)(B) (version effective Oct. 31, 2011) (same); *id.* (version effective June 1, 2012) (same); *id.* § 422.2274(b)(1)(iii)(B) (version effective July 22, 2014) (same); *id.* (version effective Mar. 16, 2015) (same); *id.* (version effective June 15, 2018) (same); *id.* § 422.2274(e)(2) (version effective Mar. 22, 2021) ("at or below the value of those services in the marketplace"); Compl. ¶¶ 80–81. CMS further declared that these payments for services other than enrollment "can be ***based on enrollment***, provided payments are at or below [fair market value]." 2019 CMS Medicare Marketing Guidelines § 110.8 (Sept. 5, 2018) (emphasis added), https://perma.cc/2VYF-5E6S; *see also* 42 C.F.R. § 422.2274(e) (version effective Mar. 22, 2021) ("Administrative payments can be ***based on enrollment*** provided payments are at or below the value of those services in the marketplace." (emphasis added)).

* * *

The law thus authorized both "compensation" payments (for enrollment services) and non-"compensation" payments (such as payments for marketing services) long before and throughout the 2016–2021 time period covered by the Government's Complaint.

C. CMS Recently Tried to Change the Rules, But Only Prospectively.

Starting in late 2023—years ***after*** the timeframe covered by the Complaint—CMS tried to make a drastic change to its longstanding payment structure on a ***prospective*** basis that would have applied to payments made in 2025 and after. CMS proposed to retire the longstanding system—which set annual dollar caps on compensation payments, but not on non-compensation payments, *see supra* pp. 6–8—and to instead treat ***all*** payments by MAOs to third parties as subject to specific annual dollar caps set by CMS. *See* 42 C.F.R. § 422.2274(a) (version effective June 3, 2024); *Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024*, 89 Fed. Reg. 30,448, 30,829 (April 23, 2024). In litigation described below, a district court in the Northern District of Texas described the change as follows:

> Until recently, CMS did not cap payments for administrative services because it did not classify payment for those services as "compensation." 42 U.S.C. § 1395w-21(j)(2)(D); *see* … 73 Fed. Reg. 54226, 54239 (Sept. 18, 2008); … 86 Fed. Reg. 5864, 5993 (Jan. 19, 2021). Instead, CMS only required that administrative payments not exceed "the value of those services in the marketplace." 42 C.F.R. § 422.2274(e)(1)–(2).
>
> This changed when CMS shifted course this year and began to set fixed rates for a wide range of administrative payments that were previously uncapped and unregulated as compensation.

AFBC, 2024 WL 3297527, at *1.

Various organizations challenged CMS's final rule in court. In July 2024, the Northern District of Texas granted in relevant part a request to stay the new regulation, reasoning that CMS appeared to have made its major changes in an arbitrary and capricious fashion due to, *inter alia*,

a lack of fair notice and insufficient attention to the reliance interests of an industry that had been following CMS's consistent approach for the prior fifteen years. *Id.* at *3–6 (reasoning that CMS ignored concerns that its rule would "possibly upend the industry").

In defending the final rule in that case, the Government acknowledged that CMS made a deliberate choice to ***change*** its longstanding approach: "CMS acknowledged that the Final Rule would 'eliminate the regulatory framework which currently allows for separate payment to agents and brokers for administrative services,' . . . CMS thus 'display[ed] awareness that it is changing position.'" *AFBC*, ECF No. 54, Gov't Brief in Support of Mot. for Summary Judgment at 26–27 (N.D. Tex. Nov. 8, 2024). The Government stated that this change was driven in part by "the value of administrative payments [including marketing payments] offered to agents and brokers . . . that CMS has observed in recent years," later citing, among other things, "information gleaned from oversight activities." *Id.* at 36 (quotation marks omitted).

On August 18, 2025, the Northern District of Texas—ruling on cross-motions for summary judgment—held that CMS had exceeded its statutory authority in its attempt to "shift[] course and set fixed rates for a wide range of administrative payments that were previously uncapped," such as payments for "launching marketing campaigns." *Americans for Beneficiary Choice v. United States Dep't of Health & Hum. Servs.*, 2025 WL 2390849, at *1–2 (N.D. Tex. Aug. 18, 2025) (*"AFBC II"*). In vacating CMS's attempt to overhaul 42 C.F.R. § 422.2274, the court reaffirmed its July 2024 ruling that CMS had acted arbitrarily and capriciously in departing from the agency's "historical positions" without addressing "reliance interests." *Id.* at *9 (quotation marks omitted).

Tellingly, the Government makes no mention of this litigation or the proposed rule change in its lengthy Complaint here.

D. Procedural History

Relator filed his original *qui tam* complaint under seal on November 2, 2021, naming a number of MAOs and TPMOs as defendants. ECF No. 1. On May 1, 2025, the Government filed its Complaint partially intervening. In it, the Government sues three MAOs (Aetna, Humana, and Elevance Health) and three TPMOs (eHealth, GoHealth, and SelectQuote). Compl. ¶¶ 6–7, 9, 10–14. The Government also sues Aetna Inc., as the parent corporation of Aetna Life Insurance Company, and CVS Health Corporation, as the (indirect) parent corporation of Aetna Inc. *Id.* ¶ 8.

The Government brings eight counts, which can be grouped into three categories:

1. FCA theories predicated on alleged violations of the AKS against all Defendants (Counts I, II, IV, VI). *Id.* ¶¶ 799–815, 828–39, 853–57.

2. FCA theories predicated on alleged violations of two non-discrimination regulations against all Defendants except for Elevance Health (Counts III, V, VII). *Id.* ¶¶ 816–27, 840–52, 858–61.

3. A federal common law claim against all Defendants for unjust enrichment, based on the same allegations as the first two categories (Count VIII). *Id.* ¶¶ 862–66.

LEGAL STANDARD

To survive a Rule 12(b)(6) motion, a complaint must state a "plausible claim for relief." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 195 n.6 (2016) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). If the "alleged conduct is merely consistent with unlawful action and is just as much in line with lawful action," *e.g.*, where there is an "obvious alternative explanation" for the alleged actions, the claim is not plausible and should be dismissed. *Frith v. Whole Foods Market*, 38 F.4th 263, 270 (1st Cir. 2022) (quotations omitted) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 554, 567 (2007)).

This Circuit follows "a two-step approach" to Rule 12(b)(6) motions, first "isolat[ing] and ignor[ing] statements in the complaint that simply offer legal labels and conclusions or merely rehash . . . elements" and next taking the "well-pled (*i.e.*, non-conclusory, non-speculative) facts

as true, drawing all reasonable inferences in the pleader's favor, and see[ing] if they plausibly narrate a claim for relief." *3137, LLC v. Town of Harwich*, 126 F. 4th 1, 8 (1st Cir. 2025) (quotations omitted); *accord United States ex rel. Flanagan v. Fresenius Med. Care Holdings, Inc.*, 142 F.4th 25, 34 (1st Cir. 2025). If factual allegations, and reasonable inferences drawn from them, fail to sufficiently address all elements of a claim, then that claim should be dismissed. *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 384 (1st Cir. 2011).

Because the FCA is a fraud statute, the Complaint also must satisfy Rule 9(b)'s heightened particularity requirement. *Escobar*, 579 U.S. at 195 n.6; *Flanagan*, 142 F.4th at 34. Rule 9(b) requires the Government to identify the "who, what, when, where, and how of the alleged fraud." *United States ex rel. Hagerty v. Cyberonics*, Inc., 844 F.3d 26, 31 (1st Cir. 2016) (citing *United States ex rel. Ge v. Takeda Pharm. Co., Ltd.*, 737 F.3d 116, 124 (1st Cir. 2013)).

To plead an FCA violation under § 3729(a)(1)(A), the Government must plead facts establishing that: (1) a claim for payment or approval was presented to the government; (2) the defendant either presented the claim or caused it to be presented; (3) the claim was false; (4) that falsity was material to the government's decision of whether to pay the claim; and (5) the defendant acted knowingly. 31 U.S.C. § 3729(a)(1)(A); *see, e.g.*, *Flanagan*, 142 F.4th at 37; *Guilfoile v. Shields*, 913 F.3d 178, 188 (1st Cir. 2019); *United States ex rel. Stonebrook v. Merck KGAA*, 2024 WL 1142702, at *7–11 (D. Mass. Mar. 15, 2024). To plead a violation of § 3729(a)(1)(B), the Government must plead facts supporting similar elements, but must show the defendant made or used, or caused to be made or used, a false statement or record related to the claim. 31 U.S.C. § 3729(a)(1)(B); *Flanagan*, 142 F.4th at 37; *Stonebrook*, 2024 WL 1142702, at *7–11.

ARGUMENT

I. THE GOVERNMENT FAILS TO PLEAD FCA CLAIMS BASED ON THE AKS.

Counts I, II, and IV of the Complaint allege FCA violations against all Defendants based on alleged predicate AKS violations. To state such a claim, the Government must plead with particularity facts establishing the elements of both an AKS violation (in order to plead the FCA element of falsity), as well as the remaining elements of the FCA claim. *See Omni Healthcare, Inc. v. MD Spine Sols. LLC*, 761 F. Supp. 3d 356, 363 (D. Mass. 2025); *United States v. Teva Pharms. USA, Inc.*, 560 F. Supp. 3d 412, 418 (D. Mass. 2021). The Government here does neither.

A. The Government Fails to Plead a Violation of the AKS.

The AKS prohibits "knowingly and willfully" paying or receiving remuneration to induce the recipient "(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or (B) to purchase, lease order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(1)–(2). The Government fails to plead an AKS violation for all of the reasons discussed below, each of which is independently fatal to the AKS-premised FCA claims in the Complaint.

1. Payments Authorized and Regulated by Congress and CMS Cannot Be Unlawful Kickbacks.

The Government's interpretation of the AKS would subject Defendants to liability for conduct that Congress and CMS ***expressly authorized***. This violates the "fundamental principle in our legal system . . . that laws which regulate persons or entities must give fair notice of conduct that is forbidden or required." *FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012).

The Government's theory is that all non-compensation payments by MAOs to TPMOs are unlawful kickbacks because such payments were designed to "induc[e] the [TPMO Defendants] to steer beneficiaries into the [MAO Defendants'] Medicare Advantage plans." Compl. at 1; *see id.* ¶¶ 98–100. But Congress contemplated that MAOs could make both "compensation" ***and*** non-"compensation" payments, including payments for marketing services, to third parties such as the TPMO Defendants. Congress then directed HHS (which delegated the job to CMS) to "establish limitations" on those payments. *Compare* 42 U.S.C. § 1395w-21(j)(2)(D) (directing HHS to set limits on permissible payments), *with id.* § 1395w-2(j)(1). And CMS has closely regulated these authorized payments ever since. *See supra* pp. 5–10.

Congress and CMS thus recognized that non-compensation payments would—lawfully—go toward marketing and services meant to affect a beneficiary's choice of an MA plan. *See* 42 U.S.C. § 1395w-21(j)(2)(D). CMS has characterized lawful MA marketing as efforts "that include steering, or attempting to steer, a potential enrollee towards a plan, or limited number of plans," *see* 2009 CMS Medicare Marketing Guidelines § 10 (Aug. 7, 2009), https://perma.cc/5WUZ-9SQR, and that are "[i]ntended to draw a beneficiary's attention to a MA plan or plans" and "[i]ntended to influence a beneficiary's decision-making process when selecting a MA plan for enrollment or deciding to stay enrolled in a plan (that is, retention-based marketing)," 42 C.F.R. § 422.2260 (version effective June 15, 2018). Payments explicitly authorized by both Congress and CMS cannot be kickbacks. Interpreting the AKS to apply to the very payments that Congress and CMS decided to ***allow*** would deprive Defendants of the fair notice that due process requires. *See, e.g.*, *United States v. Facteau*, 89 F.4th 1, 35 (1st Cir. 2023) ("[W]here an agency 'issues contradictory or misleading public interpretations' of its own regulation, 'there may be sufficient

confusion for a regulated party to justifiably claim a deprivation of fair notice.'") (quoting *United States v. Lachman*, 387 F.3d 42, 57 (1st Cir. 2004)).

The Complaint largely disregards the fact that CMS's regulations have long authorized the payments at issue here. To be clear, the Government's theory of purported falsity under the FCA is not based on violations of these longstanding regulations, but instead on purported violations of the AKS. But the language of the regulations specifically governing these payments highlights why the Government's AKS theory is not viable. CMS's regulations ***allow*** marketing and other administrative payments to be made "based on" enrollments (subject only to a fair-market-value limitation)—just not "for" enrollments (payments "for" enrollments are considered compensation subject to CMS's commission cap). 42 C.F.R. § 422.2274 (version effective Mar. 22, 2021). The Government hardly addresses this distinction. All it does is claim, in one early paragraph of the Complaint untethered to any factual allegations, that "enrollment figures may be used as a proxy" for fair market value of a marketing payment, "but cannot be paid in exchange" for enrollments. Compl. ¶ 81. But the Government never says how enrollment figures were anything other than a "proxy" for fair market value of the payments at issue here (while ignoring the issue of fair market value entirely, *see infra* pp. 21–23). *Cf. United States v. Tenet Healthcare Corp.*, 2025 WL 1166894, at *5 (6th Cir. Apr. 22, 2025) (affirming dismissal of FCA complaint because "[r]elators fail to identify the point at which a 'normal' or 'perfectly acceptable' decision to board a patient is converted into a fraudulent action"). In short, the Government runs away from the language of the governing regulations that CMS promulgated to address the payments the Government challenges, instead dressing up compliant payments as kickbacks. This is improper.

The Northern District of Texas's ruling striking down CMS's recent attempt to change this years-old payments regime reinforces these points. As the court there observed, "[u]ntil recently,

CMS did not cap payments for administrative services" such as "launching marketing campaigns." *AFBC II*, 2025 WL 2390849, at *2. CMS's proposed regulations "shifted course," abandoning the agency's "historical positions"—positions that "clearly affirmed that administrative payments were not considered compensation"—in favor of a regime that would have "set fixed rates" for marketing payments that "were previously uncapped." *Id.* at *1–2, *10. The Government cannot accuse Defendants of illegal conduct associated with "advertisements" and other marketing, *see*, *e.g.*, Compl. ¶ 54, gloss over Defendants' compliance with a years-old regulatory regime specifically governing marketing payments, fail to plausibly allege that Defendants ran afoul of that regime, ignore that CMS's efforts to ***change*** that regime prospectively were struck down as unlawful as well as arbitrary and capricious, and still maintain in the Complaint that this same conduct somehow violated the AKS.

2. Neither MA Plans nor Enrollments into MA Plans Constitute "Items," "Goods," "Services," or a "Facility," as Required to Implicate the AKS.

The AKS does not apply to every payment or receipt of "remuneration." Rather, it applies only to payments to induce (A) referrals "for the furnishing or arranging for the furnishing of any ***item or service*** for which payment may be made in whole or in part under a Federal health care program"; and (B) "recommend[ations for] purchasing, leasing, or ordering any ***good, facility, service, or item*** 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) (emphases added). The Government's AKS theory is that the MAO Defendants paid the TPMO Defendants to induce them "to steer beneficiaries" into the MAO Defendants' MA plans. Compl. at 1. But, for that alleged arrangement to be covered by the AKS in the first instance, either the MA plans or the enrollments into such plans must be a "good, facility, service, or item" within the meaning of the AKS. They are not.

The Government fails to plead facts fitting its claims within that statutory language. The Government does not explain whether it is relying on the MA plan, or instead a beneficiary's enrollment into an MA plan, as the relevant "good," "item," "service," or "facility." Instead, the Government merely quotes the AKS and then says: "The AKS does not define or otherwise restrict the broad ordinary meanings of 'item,' 'service,' or 'good.'" Compl. ¶ 26. Other than apparently conceding that a "facility" is not in play, the Government does not articulate whether or how an MA Plan or an enrollment falls into any of the other statutory categories' "broad ordinary meanings," leaving Defendants and the Court to guess. This silence alone merits dismissal. In any case, the Government cannot allege a viable AKS theory because neither an enrollment nor an MA plan constitutes a good, item, or service under basic rules of statutory construction.

When interpreting a statute, the Court must start with the text. *United States v. Millenium Lab'ys, Inc.*, 923 F.3d 240, 250 (1st Cir. 2019). Where the statutory text is ambiguous, the Court may look to context in neighboring language. *Id.* The Court also may use legislative history to confirm its interpretation. *Id.* And where ambiguity remains after examining the AKS's text, context, and structure, the rule of lenity would "require[] that ambiguities . . . be resolved in favor of the criminal defendant." *United States v. Salvador-Gutierrez*, 128 F.4th 299, 320 (1st Cir. 2025) (*en banc*) (quoting *United States v. Luna-Díaz*, 222 F.3d 1, 3 n.2 (1st Cir. 2000)); *see also Leocal v. Ashcroft*, 543 U.S. 1, 11 n.8 (2004) (ifa statute "has both criminal and noncriminal applications[, b]ecause we must interpret the statute consistently, whether we encounter its application in a criminal or noncriminal context, the rule of lenity applies"); *United States ex rel. Martin v. Hathaway*, 63 F.4th 1043, 1050 (6th Cir. 2023) (applying the rule of lenity to the AKS).

Each tool of statutory construction points in the same direction: "good, . . . service, or item" refers to ***health care products or services that a healthcare provider might supply to patients***, not

an insurance plan or the enrollment in an insurance plan. The AKS targets the corruption of healthcare provider decision-making about patient care. *See United States ex rel. Banigan v. PharMerica, Inc.*, 950 F.3d 134, 137 (1st Cir. 2020). Neither an insurance plan nor an enrollment in one implicates that issue, a reality which is confirmed by statute, regulation, and other guidance. To the best of Defendants' knowledge, no court has held otherwise.[5]

Although the AKS does not define the terms "service" or "item," HHS's Office of Inspector General ("OIG") defines these terms to encompass only products and services provided to patients in connection with their medical care. *See infra.* To start, OIG describes the AKS as encompassing arrangements "involving any item or service payable by the Federal health care programs (*e.g.*, drugs, supplies, or health care services for Medicare or Medicaid patients)." HHS-OIG, *Fraud & Abuse Laws: Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b))*, https://perma.cc/J9FX-CMX6 (last visited Aug. 16, 2025).

And more than 25 years ago, OIG promulgated regulations that included the following definition of the terms "items and services":

> [H]ealth care items, devices, supplies or services or other services reasonably related to the provision of health care items, devices, supplies or services including, but not limited to, non-emergency transportation, patient education, attendant services, social services (e.g., case management), utilization review and quality assurance. Marketing and other pre-enrollment activities are not "items or services" for purposes of this section.

42 C.F.R. § 1001.952(t)(2)(iv). Nothing in that regulation suggests that "items and services" encompasses insurance or health plans. That same regulation defined the term "health plan" as

[5] A few courts have addressed FCA claims based on allegations that payments by MAOs to others to induce MA plan enrollments violate the AKS. But those courts were not presented with (and did not otherwise address) the argument that enrollment in an MA plan is not a "good," "item," or "service" under the AKS in the first place. *See, e.g.*, *United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295 (3d Cir. 2011); *United States ex rel. Butler v. Shikara*, 748 F. Supp. 3d 1277, 1289 (S.D. Fla. 2024). Those decisions also involved alleged payments to ***healthcare providers*** (who are not supposed to be paid for beneficiary enrollments at all).

"an entity that furnishes or arranges under agreement with contract health care providers for the furnishing of ***items or services*** to enrollees, or furnishes insurance coverage for the provision of such ***items and services***, in exchange for a premium or fee . . . ." *Id.* § 1001.952(l)(2) (emphases added). If "items and services" encompassed health plans or insurance themselves, that definition would devolve into a nonsensical loop.

Neighboring statutory text confirms this reading of the terms "item" and "service." The "Definitions" chapter of the Social Security Act (which includes the AKS) uses the phrases "item or service" and "item and service" repeatedly. *See* 42 U.S.C. § 1395x. In more than fifty occurrences of these phrases, the statutory language encompasses only items and services provided to patients as part of their medical care. *See id.* For example, one section provides that "[t]he term 'medical and other health services' means any of the following ***items or services:*** (1) physician services; (2)(A) services and supplies . . . furnished as an incident to a physician's professional service . . . ; (B) hospital services . . . ; (C) diagnostic services . . . ; (J) prescription drugs . . . ." *Id.* § 1395x(s) (emphasis added). That section also states that:

> The term 'inpatient hospital services' means the following ***items and services*** furnished to an inpatient of a hospital and . . . by the hospital—(1) bed and board; (2) such nursing services and other related services, such use of hospital facilities, and such medical social services as are ordinarily furnished by the hospital for the care and treatment of inpatients, and such drugs, biologicals, supplies, appliances, and equipment, for use in the hospital, as are ordinarily furnished by such hospital for the care and treatment of inpatients; (3) such other diagnostic or therapeutic items or services . . . ; [and] (4) medical or surgical services . . . .

Id. § 1395x(b) (emphasis added); *see also id.* § 1395x(h) (describing "extended care services" to mean various care and services furnished to inpatients at skilled nursing facilities including "such other services necessary to the health of the patients"). Not one of the definitions included in 42 U.S.C. § 1395x so much as alludes to anything other than medical items and services provided to patients as part of their health care.

This statutory meaning of "items and services" is also consistent with the 2010 amendment to the AKS itself. That amendment indicates that a claim is false for purposes of the FCA if it includes "items and services" resulting from an AKS violation. 42 U.S.C. § 1320a-7b(g). Congressional statements on this amendment reflect that it was meant to "strengthen[] whistleblower actions based on ***medical care kickbacks***, which tempt health care providers to churn unnecessary medical care at great risk to patients and great cost to the taxpayer." 155 Cong. Rec. S10852, S10853 (daily ed. Oct. 28, 2009) (statement of Sen. Kaufman) (emphasis added). Congress has not used the term "items and services" to mean health insurance plans or enrollments.

This Court similarly has recognized that the AKS was designed to prohibit kickbacks for items or services provided in connection with patient care. In *United States ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 53 (D. Mass. 2011) (citing 42 U.S.C. § 1395y(a)(1)(A)), the Court noted Medicare "relies on providers to seek payment only on items or services 'reasonable and necessary for the diagnosis or treatment of illness or injury'" and that the AKS is designed to deter payments that influence this "medical judgment." More broadly, courts recognize the AKS aims to "prevent medical providers from making decisions based on improper financial incentives rather than medical necessity and to ensure that federal health care programs do not bear the costs of such decisions." *United States ex rel. Banigan v. PharMerica, Inc.*, 950 F.3d 134, 137 (1st Cir. 2020); *see also United States v. Patel*, 778 F.3d 607, 612 (7th Cir. 2015) (the AKS "protect[s] patients from doctors whose medical judgments might be clouded by improper financial considerations") (citations omitted). Because the Government has failed to—and cannot—plead that MA plans or enrollments into such plans constitute goods, items, or services under the AKS, the Government's AKS-based claims must be dismissed.

3. The Government Fails to Allege Prohibited Remuneration.

The Government does not allege, nor could it, that payments from MAOs to third parties in exchange for marketing services are impermissible remuneration. Indeed, as discussed, such payments are expressly permitted. *Supra* pp. 5–10. Nor could the Government allege that the TPMO Defendants did not, in fact, provide marketing services, which aim to "draw a beneficiary's attention to a MA plan or plans" and "influence a beneficiary's decision-making process." 42 C.F.R. § 422.2260(1). The Government nevertheless contends the MAOs paid too much money to the TPMOs, rendering those payments "kickbacks." But the Government wholly fails to allege that the payments at issue exceeded the value of those services in the marketplace (*i.e.*, fair market value). This is fatal, both under the AKS generally and because fair market value is the limiting principle CMS established to police precisely the payments at issue here. *Supra* p. 8.

To plead an AKS violation, the Government must allege that MAO Defendants offered or paid "remuneration." 42 U.S.C. § 1320a-7b(b)(2). A payment does not count as "remuneration" under the AKS if the payment simply was fair market value for the good or service purchased. *See Millenium Laboratories*, 923 F.3d at 254 (highlighting relator's failure to allege pricing below fair market value in AKS-based FCA claim); *Bingham v. HCA, Inc.*, 783 Fed. App'x 868, 873 (8th Cir. 2019) ("[F]air market value . . . is . . . something Relator must address in order to show that HCA offered or paid remuneration to physician tenants."); *accord Vargas v. Lincare, Inc.*, 134 F.4th 1150, 1161–62 (11th Cir. 2025) ("The upshot is that the relators never pleaded . . . why the compensation—paid for services rendered—should be viewed as anything other than payment for work done."); *United States v. Wood*, 2024 WL 3742713, at *4–5 (S.D. Ga. Aug. 9, 2024); *United States v. Northwestern Memorial Healthcare*, 2023 WL 6388328 at *5 (N.D. Ill. Sept. 29, 2023);

Klaczak v. Consol. Med. Transp., 458 F. Supp. 2d 622, 679 (N.D. Ill. 2006).[6] Here, the Government does not allege that any payment to a TPMO for marketing services provided by that TPMO exceeded fair market value. Indeed, as to Aetna, the Government alleges payments had to "increase" to match the market. Compl. ¶¶ 410, 419.

The absence of any allegation regarding fair market value is not just telling, it is fatal. After all, CMS decided that fair market value is the method to police ***exactly what the Government is complaining about in this case***: marketing payments allegedly designed to circumvent CMS's regulatory limit (*i.e.*, a specific dollar cap) on compensation "for enrollments." *See, e.g.*, Compl. at 1–2. As discussed, administrative payments for (non-enrollment) services, such as marketing payments, can be "based on" enrollments and ***the only limitation is that they must not exceed fair market value for the service in question***. 42 C.F.R. §422.2274(e)(1)–(2) (version effective Mar. 22, 2021); *see id.* § 422.2274(a)(1)(iv) (version effective Sept. 1, 2011 to Mar. 22, 2021).[7]

CMS has repeatedly—and as recently as late 2024—emphasized that it chose fair market value as the tool to limit marketing and other types of administrative payments:

> When CMS announced its final guidelines in 2008, it imposed a fair-market-value limit on compensation to support administrative activities, while promising to monitor administrative payments in case Medicare Advantage and Part D drug plans used them to get around other compensation limits. For years, CMS was satisfied that the fair-market-value limitations met the agency's statutory obligation to protect beneficiaries.

[6] This case is markedly different from *Bay State Ambulance & Hosp. Rental Serv., Inc.*, which involved remuneration in the form of cars and cash, including because the rules here are prescribed by regulation, and those regulations authorize payments tied to fair market value. 874 F.2d 20, 33 (1st Cir. 1989).

[7] Prior to March 2021, CMS also required that such payments "must not exceed an amount that is commensurate with the amounts paid by the MA organization to a third party for similar services during each of the previous 2 years." *See, e.g.*, 42 C.F.R. § 422.2274(b)(1)(iv)(B) (version effective June 15, 2018). Just as the Government does not allege that any payment exceeded fair market value, the Government does not allege that any payment exceeded this limitation.

AFBC, ECF No. 54, Gov't Br. in Support of Mot. for Summary Judgment at 2 (N.D. Tex. Nov. 8, 2024); *see id.* at 8–9 ("Thus, by the end of 2008, CMS regulated all payments to agents, brokers, and third-party marketing organizations based on fair-market value, regardless of whether they were payments for the sale or renewal of a policy or administrative payments."); *id*. at 9 ("While concerns about third-party marketing organizations—especially bidding wars—persisted, CMS continued to rely on its fair-market-value cap to control administrative payments, rather than setting a specific dollar cap, as it did for other compensation.").

What's more, in the Northern District of Texas litigation over CMS's recent attempted rule change, the Government took the position that CMS's regulation permitting MAOs to pay TPMOs for marketing services up to "fair-market value" was too "vague" to police "the compensation cap." *AFBC*, Gov't Br. in Support of Mot. for Summary Judgment at 10–11 (N.D. Tex. Nov. 8, 2024). A line that the Government itself deems too "vague" to sort permissible from impermissible payments cannot trigger FCA and AKS liability. *Cf. CFTC v. EOX Holdings, LLC*, 90 F.4th 439, 444 (5th Cir. 2024) ("If a violation of a regulation subjects private parties to criminal or civil sanctions, a regulation cannot be construed to mean what an agency intended but did not adequately express." (quotation marks omitted)). To be sure, the Government may ***disagree*** with the structure CMS put in place for nearly twenty years, but that disagreement cannot support an FCA claim. *See D'Agostino v. ev3, Inc.*, 845 F.3d 1, 8 (1st Cir. 2016) ("The FCA exists to protect the government from paying fraudulent claims, not to second-guess agencies' judgments about whether to rescind regulatory rulings.").

In sum, the absence of allegations concerning the fair market value of the services for which the challenged payments were made requires dismissal. The Government's theory would convert compliant payments into kickbacks, contradicting the AKS and CMS's own regulations.

4. The Government Fails to Allege Prohibited Inducement.

The AKS prohibits paying or receiving remuneration to induce the recipient "to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service 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)(b); *see id.* § 1320a-7b(b)(1)(A). This prohibition "primarily targets payments to individuals with influence over or access to patients that lets them control or influence the patients' choices about medical care." *United States v. Sorensen*, 134 F.4th 493, 499 (7th Cir. 2025); *see id.* at 499 ("The typical example is a physician who accepts money in exchange for sending patients to a particular healthcare provider such as a hospital or specialist."); *id.* at 500 (cases against "non-physicians" are "much less common").

Not "every sort of influence is improper." *Id.* at 502. "[A]ggressive advertising efforts are not equivalent to unlawful referrals of patients." *Id.* at 504. For that reason, the Seventh Circuit in *Sorenson* recently distinguished such marketing payments—which it found did ***not*** violate the AKS—"from payments to individuals who take advantage of their existing relationships with patients or . . . providers." *Id.* at 501. The Court reasoned in part that the advertisers there had made requests for medical services on behalf of patients "[w]ith patients' consent" and in a manner that left "full discretion" in the hands of decisionmaker physicians. *Id.* Acknowledging that cases in which the decisionmaker "rubber stamps" the input of an advertiser may be different, the Court recognized also that marketing without more does not violate the AKS: "After all, the purpose of advertising is to influence decision making." *Id.* at 502–03 (citing, *inter alia*, *United States v. Marchetti*, 96 F.4th 818, 827 (5th Cir. 2024) ("What are advertisers hired to do anyway?")). *Sorenson*'s language echoes CMS's own regulations about the ***legitimate*** purpose of "marketing" in the MA context—one of the core functions a TPMO (a third-party ***marketing*** organization) provides to an MAO. *See* 42 C.F.R. § 422.2260.

Here, the MAO Defendants did not pay physicians or potential enrollees to induce referrals; they paid marketers (the TPMO Defendants) to market. Moreover, the Government—far from alleging marketing was "rubber stamped" by enrollees—alleges that the TPMO Defendants would apply for enrollment on a beneficiary's behalf only "***if the beneficiary gave her consent***." Compl. ¶ 58 (emphasis added). The Complaint does not allege that even one beneficiary was enrolled in a plan not of their choosing as a result of the alleged scheme. At most, the Government alleges "[a]ggressive marketing efforts" by the TPMOs. *Sorensen*, 134 F.4th at 504 (finding these efforts did not violate the AKS); *see* Compl. ¶ 744 (alleging "aggressive sales tactics"). That is not within the scope of the AKS. Indeed, simply trying to "[d]raw a beneficiary's attention to a MA plan or plans" or "[i]nfluence a beneficiary's decision-making process when making a MA plan selection" falls squarely within CMS's definition of "[m]arketing" and are part of what CMS expects—and has long expected—TPMOs to be paid by MAOs to do. *See* 42 C.F.R. § 422.2260.

B. The Government Fails to Plead a Violation of the FCA Related to its AKS Allegations.

The Government also fails to plead the elements necessary to connect any alleged AKS violation to FCA liability under either of the "two pathways to FCA liability for an AKS violation" that this Circuit has recognized. *Flanagan*, 142 F.4th at 35. One path—the "false certification" theory that the Government pursues in Counts II and IV—arises "when someone falsely represents compliance with a material requirement that there be no AKS violation in connection with the claim." *Id.* (quoting *United States v. Regeneron Pharms., Inc.*, 128 F.4th 324, 333 (1st Cir. 2025)).[8] Here, the Government fails to plead the materiality and particular-false-claim elements

[8] Defendants preserve their contention that the First Circuit erred in recognizing this as a pathway to AKS-based FCA liability. *See United States ex rel. Martin v. Hathaway*, 63 F.4th 1043, 1052 (6th Cir. 2023) ("When it comes to violations of the [AKS], only submitted claims 'resulting from' the violation are covered by the False Claims Act."); *United States ex rel. Louderback v. Sunovion Pharms, Inc.*, 703 F.

of a false certification theory. The other path, which the Government pursues in Count I, is "when claims for payment are made 'resulting from' AKS violations." *Id.* (quoting 42 U.S.C. § 1320a-7b(g)). Here, the Government fails to plead the but-for causation required to sustain this theory.

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.

To plead its false certification theory, the Government must allege that Defendants' claims "misrepresent[ed] compliance with a 'statutory, regulatory, or contractual requirement' that 'the defendant knows is material to the [g]overnment's payment decision.'" *Regeneron*, 128 F.4th at 332 (quoting *Escobar*, 579 U.S. at 181). The materiality standard is "demanding," and materiality must be pled with "plausibility and particularity." *Guilfoile*, 913 F.3d at 187 (quoting *Escobar*, 579 U.S. at 194, 195 n.6). And, as this Court recently held, failure to meet that pleading standard requires dismissal of a false certification claim. *See Stonebrook*, 2024 WL 1142702, at *9–10. This case similarly should be dismissed because the Government—after years of investigation—makes only conclusory allegations that parrot the legal standard for materiality.

"[M]ateriality 'look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.'" *Escobar*, 579 U.S. at 193 (quoting 26 R. Lord, Williston on Contracts § 69:12, p. 549 (4th ed. 2003)). The Government must allege facts showing "'the government's response to noncompliance with the relevant contractual, statutory, or regulatory provision.'" *United States ex rel. Foreman v. AECOM*, 19 F.4th 85, 111 (2d Cir. 2021) (quoting *United States v. Strock*, 982 F.3d 51, 62 (2d Cir. 2020)); *accord Escobar*, 579 U.S. at 194–95. The Government can do so by alleging that "the defendant knows that the Government consistently refuses to pay

Supp. 3d 961, 979–80 (D. Minn. 2023) ("The statute is better construed to mean that a False Claims Act case premised on an underlying [AKS] violation must satisfy § 1320a-7b(g)'s requirements.").

claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement." *Stonebrook*, 2024 WL 1142702, at *10 (quoting *Escobar*, 579 U.S. at 194–95). The Government cannot credibly allege that here because there is no such evidence of the Government refusing payment.[9] After all, the Government is applying the AKS to payments that were authorized and closely regulated by CMS for years. That leaves the Government with "conclusory allegations as to materiality" that simply assert that the false claims "were material to the U.S. government's decision to purchase"—that is insufficient as a matter of law. *Id.*

Because the Government cannot point to a single instance in which it refused payment when faced with similar violations, it simply asserts, with no supporting factual allegations, that the alleged violations "were material to the Government's payment decision." Compl. ¶ 782; *see also, e.g.*, *id.* ¶¶ 766, 790, 800, 805, 808, 817, 820, 822, 829, 832, 834, 841, 845, 847. These are precisely the kinds of "conclusory allegations as to materiality" that this Court, *Stonebrook*, 2024 WL 1142702, at *10, and the Supreme Court, *Escobar*, 579 U.S. at 181, have deemed insufficient. In *Stonebrook*, for example, "[n]owhere" did the plaintiff "allege that the government refused to pay . . . due to" the specific noncompliance that was alleged. WL 1142702, at *10. Instead, the plaintiff relied on the conclusory allegation that the supposed falsehoods "were material to the U.S. government's decision to purchase." *Id.* Here, the Government likewise makes no factual allegation about CMS's response to any payment akin to those it alleges here, and instead makes a handful of conclusory recitations of the word "material."

[9] CMS has an administrative sanctions regime tailored to deal with violations related to the MA program, *see*, *e.g.*, 42 C.F.R. § 422.752(a), and the Complaint here does not even allege that CMS invoked ***this*** set of tools in response to the marketing payments at issue or any similar payments. Nor did the government address that CMS only has authority to issue administrative sanctions due to marketing violations. *See id.* The Government cannot plead that a marketing violation will result in non-payment by CMS, and they have failed to do so here.

The pleading failure in this case is even more glaring than in *Stonebrook* because CMS here ***was aware of*** the exact kinds of marketing payments that Defendants are accused of making, *see infra* pp. 28–29, and yet continued to pay the MAO Defendants capitated payments for enrolled MA beneficiaries, *see, e.g.*, Compl. ¶¶ 791–98. That conclusively undermines the Government's attempt to plead materiality, especially in light of the Supreme Court's holding that, "if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence those requirements are not material." *Escobar*, 579 U.S. at 195; *see also Zotos v. Town of Hingham*, 98 F.4th 339, 345–46 (1st Cir. 2024) (noting "strong evidence" that "the requirements in question were not material" where government agency was made aware of alleged conduct and did not withhold funding). That CMS ***continued to pay*** MAOs forecloses any suggestion of materiality, as a matter of law.

All of this is plain from the Complaint and the Northern District of Texas litigation. The Complaint describes CMS's longstanding regulatory framework, which ***authorized*** the marketing-related payments from MAOs to TPMOs that the Complaint now generically claims were materially fraudulent. *See* Compl. ¶¶ 52–83; *supra* pp. 5–10. The Government has made clear that, for years, CMS has been aware of the kinds of marketing payments that MAOs were in fact making to TPMOs. *See AFBC*, ECF No. 54, Gov't Br. in Support of Mot. for Summary Judgment at 36 (N.D. Tex. Nov. 8, 2024) (acknowledging CMS awareness of "the value of administrative payments offered to agents and brokers . . . that CMS has observed in recent years"); *id.* ECF No. 58, Gov't Reply Br. in Support of Mot. for Summary Judgment 18 (noting CMS awareness "that agents and brokers are being paid, typically through various purported administrative and other add-on payments, amounts that cumulatively exceed the maximum compensation allowed under the current regulations"). And the Complaint alleges that CMS has continued over time to review

and adapt its marketing-payment regulations. Compl. ¶¶ 80–81. While the Complaint ignores CMS's most recent attempted regulatory change—which was stayed due to its about-face from prior law and ultimately vacated—the Complaint does not and cannot allege that CMS has ever stopped making capitated payments to MAOs. This precludes a finding of materiality. *See United States ex rel. Bierman v. Orthofix Int'l, N.V.*, 177 F. Supp. 3d 712, 715 (D. Mass. 2016) ("[P]ronounced absence of estimated length of need from lists of criteria developed to guide Medicare's reimbursement decisions demonstrates that Medicare does not consider estimated length of need material to those decisions."); *United States ex rel. Gugenheim v. Meridian Senior Living, LLC*, 2020 WL 1932435, at *4 (E.D. N.C. Apr. 21, 2020) (no materiality where Medicaid "sanctioned guidance" and billing related forms did not require the information).

Nor did the Government plead that the alleged violation in this case "goes to 'the very essence of the bargain.'" *Zotos*, 98 F.4th at 344 (quoting *Escobar*, 579 U.S. at 193 n.5). This factor looks to the "impact" the alleged falsehood had "on the goals of the contract." *United States ex rel. Bonzani v. United Techs. Corp.*, 662 F. Supp. 3d 217, 232 (D. Conn. 2023) (quoting *United States ex rel. Yu v. Grifols USA, LLC*, 2022 WL 7785044, at *4 (2d Cir. 2022)); *see Foreman*, 19 F.4th at 117 (violation immaterial where the alleged falsity "do[es] not necessarily undermine the . . . Contract's core purpose"). As the Eighth Circuit has held, "[m]arketing violations" related to MA plans "likely do not hinder CMS's or a carrier's ability" to satisfy their respective obligations. *Holt*, 2022 WL 3587358, at *7 (violations of MA sales and marketing regulations "do not go to the essence of the bargain because none of the alleged violations led to the enrollment of someone who was ineligible for Medicare, misled an enrollee about the benefits of a particular plan, or led to someone who was eligible for Medicare not receiving benefits"); *see also Spay v. CVS Caremark Corp.*, 875 F.3d 746, 765 (3d Cir. 2017) (holding that technical violations of Medicare or Medicaid

requirements were immaterial where "[t]he government did not pay for services that were not provided, and the Sponsors did not receive any compensation for prescriptions that were never given to Medicare recipients"); *United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 310 (3d Cir. 2011) (affirming dismissal based on lack of materiality and noting that "the Government has established an administrative mechanism for managing and correcting Medicare marketing violations which includes remedies for violations other than the withholding of payment otherwise due"); *United States ex rel. Mbabazi v. Walgreen Co.*, 2021 WL 4453600, at *6 (E. D. Pa. Sept. 28, 2021) (no FCA liability due to lack of materiality in managed care case, where there was no allegation the false claim affected the capitated rate of reimbursement paid by CMS). At no point in the Complaint does the Government allege that the MAO Defendants failed to provide what was at the essence of the bargain with CMS—coverage for eligible beneficiaries seeking to enroll in MA plans.

The Government similarly cannot rely on a catchall regulation stating that MAOs will comply with all contractual and regulatory provisions and designating them "material to the performance of the MA contract." Compl. ¶ 769; *see* 42 C.F.R. § 422.504(a). That catchall is broad "incorporat[ion] by reference" that does not transform every cited provision into a payment condition. *Yu*, 2022 WL 7785044, at *3. The Supreme Court has rejected the idea that liability can be created in this way:

> [I]f 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. The argument that 42 C.F.R. § 422.504(a) transforms other regulations into conditions of payment is an "extraordinarily expansive view of liability" that "is not supported

by the False Claims Act." *United States ex rel. Nedza v. Am. Imaging Mgmt., Inc.*, 2019 WL 1426013, at *7 (N.D. Ill. Mar. 29, 2019). And even if they were conditions of payment, that alone would not establish materiality. *See Escobar*, 579 U.S. at 178, 194.

Because the Government fails to plead materiality, Counts II and IV must be dismissed.

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

The Government also fails to identify "an actual false claim," *Guilfoile*, 913 F.3d at 188, the "*sine qua non* of a False Claims Act violation," *Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 225 (1st Cir. 2004). To plead falsity, the Government must, in its words, plead "a nexus between AKS violations and specific claims for federal reimbursement." United States Br. as *Amicus Curiae*, *Flanagan*, 2023 WL 5526783, at *20 (1st Cir. Aug. 21, 2023); *see Flanagan*, 142 F.4th at 37 (affirming dismissal where relator did not "plead with particularity the connection between false records and/or statements and the intent to have a false claim paid for by the government programs"); *United States ex rel. VIB Partners v. LHC Grp., Inc.*, 2025 WL 1103997, at *3 (6th Cir. Apr. 14, 2025) (affirming dismissal for failure to plead "direct connection" between alleged fraud and specific claims for payment); *United States ex rel. Walsh v. Eastman Kodak Co.*, 98 F. Supp.2d 141, 147 (D. Mass. 2000) ("Without citing a single false claim ***arising from*** an allegedly false invoice, Relator has not met even a bare-bones 9(b) test.") (emphasis added). The Government also must connect the specific claims to a certification that "falsely represents compliance" ***"in connection with"*** the alleged AKS-violative claims. *Regeneron*, 128 F.4th at 333 (emphasis added). Taken together, the Government must: (a) connect an AKS violation to a specific claim; and (b) connect a certification of compliance to a non-compliant claim such that the certification is false. The Government satisfies neither requirement here.

Preliminarily, the Government is vague as to what the "claims" at issue here are and waits until late in the Complaint to hint at its view. Eventually, the Complaint seems to allege that the

claims are both the MAOs' periodic submissions of enrollment data to CMS ***and*** the enrollments themselves. Compl. ¶¶ 780–81. As to the latter, the Government asserts, citing nothing, that each enrollment "constituted presentment of a claim" because an enrollment is "initiation of a demand" for capitated payments. *Id.* ¶ 780. This is wrong. A claim under the FCA is an actual "request or demand . . . for money or property" from a government payor, and an enrollment in an MA Plan is neither. 31 U.S.C. § 3729(b)(2). As to the former, to the extent submission of enrollment data and associated certifications comprise a "claim," the Government fails to identify—as it must—a link between a "kickback" and any specific beneficiary included in the "claim" that would render any certification of compliance false.

The Government claims to provide "Examples of False Claims" in the form of several bulleted lists and charts of beneficiaries. Then it states without elaboration that ***all*** of these beneficiaries "were enrolled pursuant to the above-described kickbacks." Compl. ¶¶ 791–98. That *ipse dixit* does nothing to connect the exemplar "claims" to any alleged AKS violation—much less the who, what, when, where, and how of that connection, as required by Rule 9(b). In the following illustrative example related to Humana and eHealth, the Government alleges, "For each of the following beneficiaries who were enrolled pursuant to the above-described kickbacks, Humana submitted claims for payment to CMS . . . ," and then provides bullets and a chart of beneficiary enrollments. *Id.* ¶ 793. However, neither the words nor the chart alleges any fact that, if proved, would show any relationship between any of the enrollments and an AKS violation, as would be required to sufficiently plead that any certifications were false. *Id.* For instance, here is the bullet and chart entry for "Beneficiary 37":

- In February 2016, under its contract H6622 and plan Humana Gold Plus, Humana submitted a claim with beneficiary data to CMS, including data related to Beneficiary 37. Humana received payment pursuant to this claim. In total, Medicare paid $12,477.00 to Humana for Beneficiary 37 in the year of Beneficiary 37's enrollment.

Beneficiary	Defendant Broker	Defendant Insurer	Plan Name	Application Date; Effective Enrollment Date	CMS Payment to Insurer (Year of Enrollment)
37	eHealth	Humana	Humana Gold Plus	Feb. 19, 2016; Mar. 1, 2016	$12,477.00

Id. Beneficiary 37 is not mentioned again.

The Government repeats this formula for every other MAO-TPMO pairing. *Id.* ¶¶ 791–98. The only conceivable nexus between the exemplar "claims" and the alleged AKS violations is that the beneficiaries (like Beneficiary 37) enrolled in one of the MAO Defendants' MA plans during the 2016-2021 timeframe that the Government alleges a kickback scheme existed.[10] The Government's theory rests on raw speculation that ***every single enrollment*** during the relevant timeframe by three of the nation's largest MAOs for beneficiaries who enrolled via three of the nation's largest TPMOs is *de facto* fraudulent, regardless of any connection between a specific enrollment (or subsequent submission to CMS including that enrollment) and an alleged AKS violation. *See Ge*, 737 F.3d at 124 (affirming dismissal where relator "made no attempt . . . to allege facts that would show that some ***subset*** of claims . . . was rendered false as a result of [the] misconduct" (emphasis in original) and rejecting notion that "***all*** claims submitted during this

[10] The Complaint's subsection titled "The Defendants' Kickback Schemes Harmed Medicare Beneficiaries" showcases the anomalies that flow from the Government's apparently unbounded view of the FCA's "nexus" requirement. Compl. ¶¶ 743–64. For example, the Government alleges in "October 2019, a Medicare beneficiary complained that an eHealth agent had convinced him to switch from a Humana Medicare Advantage plan to a Wellcare Medicare Advantage plan, only to learn the Wellcare plan's provider network did not include his health care providers." *Id.* ¶ 759. The Government alleges that Humana—the MAO an eHealth agent allegedly encouraged the customer to ***leave***—paid kickbacks to eHealth. *Id.* ¶¶ 257 *et seq.* As for Wellcare—the MAO the Government alleges the beneficiary was steered ***toward***—the Government investigated Wellcare and then opted ***not*** to intervene in the relator's case as to Wellcare. ECF No. 34. That means the example touted by the Government of a supposed harm caused by the alleged kickback schemes involves eHealth steering a customer ***away from*** an entity paying a supposed kickback to an entity that did not. The Government seems to assume that all "harms"—several of which seem to involve little more than allegedly suboptimal customer support—between 2016 and 2021 automatically have a nexus to alleged kickbacks. That is not a tenable view of FCA liability.

period were false" (emphasis added)); *Vargas*, 134 F.4th at 1160 (affirming dismissal of *qui tam* complaint for failure to plead connection between alleged co-pay waivers and specific claims for payment); *United States v. Atlanta Primary Care Peachtree, PC*, 2025 WL 1823269, at *6 (11th Cir. July 2, 2025) ("[E]ven if McKoy has sufficiently alleged that Dr. Bennett's alleged distinctions between insured and uninsured patients ***could*** produce a false claim . . . she never sufficiently links that scheme to a [claim]….") (emphasis in original).

The Government's approach to its false certification theory—identify an alleged kickback scheme, identify exemplar enrollments and certifications, and provide no link between (a) the enrollments or the certifications, and (b) an AKS violation—has been routinely rejected.[11] The First Circuit recently rejected this approach again in *Flanagan*. 142 F.4th 25. There, the relator alleged a kickback scheme involving a dialysis provider's efforts to induce referrals from hospitals and providers. *Id.* at 29–31. The relator alleged that the dialysis provider periodically certified compliance with the AKS and pointed to "allegedly tainted referrals," but the First Circuit affirmed dismissal of these claims for failure to tie the certifications to any claims that were "tainted by the kickback scheme." *Id.* at 37. This type of approach was likewise rejected by the Eleventh Circuit in *United States ex rel. Senters v. Quest Diagnostics, Inc.*, 2025 WL 1951196 (11th Cir. July 16,

[11] The chronology of this case may explain why the Government's case is so ill-suited to a false certification theory. When the Relator filed the original qui tam complaint in November 2021, it was an open question in the First Circuit whether "resulting from" in 42 U.S.C. § 1320a-7b(g) meant a claim need only be exposed to a contemporaneous AKS violation to be per se false under the FCA (a view adopted by the Government in other litigations) or if FCA claimants must meet the more demanding but-for causation standard. The same was true at the time the Government partially intervened in January 2025. However, on February 18, 2025, the First Circuit joined other Circuits when it issued a decision in *United States v. Regeneron*, which held the "but-for cause" standard applies, rejecting the Government's years-old view that "all that is required" is "expos[ure] to an illegal recommendation or referral." 128 F.4th at 331. As another court in this district recently observed, *Regeneron* "amounted to a critical shift in the . . . law" that "undeniably made proving an FCA claim under the 2010 amendment more difficult." *United States v. Regeneron Pharma. Inc.*, --- F. Supp. 3d ---, 2025 WL 2207299, at *5 (D. Mass. Aug. 4, 2025). Just over two months after *Regeneron*, the Government filed its Complaint here, which mostly jettisons a serious effort to meet the but-for standard (*infra* pp. 35–37) and struggles to cram inapposite facts into the false certification mold.

2025). There, the relator claimed a seller of laboratory tests had engaged in a scheme to deceive providers into prescribing medically unnecessary tests and pointed to an "exemplar" certification where the seller certified to CMS that the tests were medically needed. *See id.* at *3. The Eleventh Circuit affirmed the dismissal of false certification claims, reasoning in part that the exemplar had not tied a certification to an underlying falsity. *See id.* at *3 (finding the "exemplar sample for Patient Y" was coupled with a certification of medical necessity but there were "no particular facts to show why the custom panel for Patient Y was not medically necessary and why, therefore, any certification to the contrary was false"). As with *Flanagan*, *Senters*, and other cases in which "charts" of assembled claims fail to "remedy the disconnect between the alleged underlying conduct and any actual false claims," the Government fails to identify any specific claim tainted by an AKS violation ***or*** any certification of compliance concerning an AKS-tainted claim. *Health Choice Alliance, LLC ex rel. United States v. Eli Lilly & Co.*, 2018 WL 4026986, at *55 (E.D. Tex. July 25, 2018), *report & recommendation adopted*, 2018 WL 3802072 (E.D. Tex. Aug. 10, 2018). Both are required to plead a false certification claim.

Because the Government fails to plead falsity, Counts II and IV must be dismissed.

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

In Count I, the Government pursues the path to AKS-based FCA liability that requires it to plead "that the AKS violation was a but-for cause of the false claim." *Regeneron*, 128 F.4th at 328; *see* Compl. ¶¶ 799–803. This standard is not met simply by alleging beneficiaries were "exposed to" an AKS violation. *Regeneron*, 128 F.4th at 327, 331 (quotation marks omitted). Nor may the Government rely on "generalized allegations that the scheme must have, as a matter of logic, resulted in false claims." *United States ex rel. Flanagan v. Fresenius Medical Care Holdings, Inc.*, 2022 WL 17417577, at *1 (D. Mass. Dec. 5, 2022); *accord United States v. Exagen, Inc.*, 2025 WL 959460, at *10 (D. Mass. Mar. 31, 2025) (denying motion to amend FCA complaint

on futility grounds due to failure to plead facts plausibly establishing but-for causation). Instead, the Government must allege sufficient facts to support—under Rule 9(b)'s heightened standard—the inference that the "referrals resulted from the alleged kickback scheme," *Flanagan*, 142 F.4th at 36, and "would not have occurred" ***but for*** the alleged kickbacks, *Regeneron*, 128 F.4th at 329 (cleaned up) (quoting *Univ. of Tex. Sw. Med. Ctr. v. Nassar*, 570 U.S. 338, 346–47 (2013)); *see Martin*, 63 F.4th at 1053 (but-for cause not plausibly alleged where there was "not one claim for reimbursement identified with particularity in this case that would not have occurred anyway").

The Government has not alleged that any specific AKS violation was the but-for cause of any specific claim. That dooms the Government's "resulting from" theory of FCA liability under 42 U.S.C. § 1320a-7b(g). The Government relies on overarching allegations that Defendants perpetrated at least nine parallel kickback schemes (with all three Defendant TPMOs involved in three independent schemes with all three MAO Defendants, Compl. ¶¶ 98–742), lists exemplar claims with no description of the circumstances surrounding those claims (*id.* ¶¶ 791–98), and then offers a blanket allegation that the beneficiaries underlying the claims were "enrolled pursuant to the above-described kickbacks" (*id.*). *See supra* pp. 32–33 (excerpting from the exemplar claim charts and bullets). It is telling that the Government can only bring itself to claim that beneficiaries were enrolled "pursuant to" kickbacks, rather than that the kickbacks were the ***but-for cause*** of the enrollments. That is, at best, a redo of the causation theory the Government pressed but the First Circuit squarely rejected in *Regeneron*. *See* 128 F.4th at 327, 331.

The Complaint is devoid of ***any*** allegation as to ***how*** the exemplar claims "resulted from the alleged kickback scheme" or "would not have occurred" but for a kickback. *Flanagan*, 142 F.4th at 35, 36. That gap stands in stark contrast to what would be required here for the Government to allege but-for cause. At minimum, the Government would need to allege:

(a) a marketing payment from an MAO Defendant to a TPMO Defendant;

(b) that the marketing payment caused the TPMO Defendant to take a marketing action (*e.g.*, a specific marketing campaign running a television advertisement);

(c) that one or more specific individuals saw the marketing action; and

(d) that the individual(s) enrolling in a plan administered by the MAO Defendant would not have done so but for the particular marketing action at issue.[12]

To allege even ***one*** FCA violation, the Government would need to plausibly allege that at least one beneficiary enrolled in an MA plan other than the plan the beneficiary would have selected, but-for an unlawful marketing payment ***and*** that a claim was made on behalf of this beneficiary. The Government makes no effort to allege any part of this chain, much less all of it. *See, e.g.*, *Exagen*, 2025 WL 959460, at *10 ("[The complaint] largely describes the purported kickback scheme and then seemingly asks the Court to infer that the scheme led to the use of Exagen's tests. Accordingly, [it] fails to adequately plead causation.").

Because the Government has not pleaded but-for causation, Count I must be dismissed.

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

The Complaint's discrimination-based FCA claims (Counts III, V, and VII) are unprecedented. The Government contends that all Defendants other than Elevance Health presented or caused to be presented "claims for payment that falsely represented compliance with material statutory, regulatory, or contractual requirements" or conspired to do so, naming 42 C.F.R. § 422.110 and 45 C.F.R. Part 92 as the regulations at issue. *See* Compl. ¶¶ 817–19, 841–44. These provisions have their own enforcement mechanisms, none of which have been pursued. It is perhaps for that reason that the shoe does not fit here: these claims fail because the Government

[12] Even if the Government could satisfy each link in this causal chain, it is not clear how the Government could plead around its own concession that an enrollment would only take place "[i]f the beneficiary gave her consent." Compl. ¶ 58.

fails to plead four independently dispositive elements of its FCA theories and also fails to plead entitlement to the recovery of actual or treble damages. ***First***, the Government does not connect its theory of purported regulatory violations to even a single false "claim." To the contrary, the Government's theory is that Defendants' alleged violations resulted in claims ***not*** being presented. ***Second***, the Government fails to allege conduct that violated either of the two non-discrimination regulations it invokes, and thus cannot plead "falsity." ***Third***, the Government fails to allege that the particular regulatory violations it pleads were "material." ***Fourth***, the Government fails to allege that any violation of non-discrimination regulations caused it any loss—again, because its entire theory is that Defendants caused claims ***not*** to be submitted. ***Finally***, even if the Government had pleaded the foregoing elements, it fails to allege that it suffered any damages, which requires dismissal of the Government's claim for actual and treble damages.

A. The Government Fails to Plead Particular False Claims.

The Government's non-discrimination theory does not state a cognizable claim under the FCA because it posits that discrimination prevented unidentified individuals from enrolling in an MA plan, and as a result Defendants ***did not*** submit claims on their behalf. *See, e.g.*, Compl. ¶¶ 484–90. The FCA is "not an all-purpose antifraud statute," *Escobar*, 579 U.S. at 194, and "[l]iability under the [FCA] arises from the submission of a fraudulent claim to the government." *Urquilla-Diaz v. Kaplan Univ.*, 780 F.3d 1039, 1045 (11th Cir. 2015) (quoting *Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1012 (11th Cir. 2005)). The Government therefore "must sufficiently plead facts supporting the existence of an actual false claim." *Guilfoile*, 913 F.3d at 188 (citing *Karvelas*, 360 F.3d at 225). The allegation that Defendants did not submit claims when (in the Government's view) they should have places this theory outside the ambit of the FCA. *See Stonebrook*, 2024 WL 1142702, at *7 ("Because FCA liability attaches only to false *claims*, merely alleging facts related to a defendant's alleged *misconduct* is not enough.") (quoting *Ge*, 737 F.3d at 124)

(emphasis in original). Indeed, the Government's discrimination theory is the opposite of the type of factual situation the FCA covers (the submission of an actual claim for payment).

As a result of this mismatch, the Government cannot plead the necessary existence of false claims at all, much less with the "particularity" required by Federal Rule of Civil Procedure 9(b). *Id.* at *1. This standard requires it to plead the "submission of claims based on those practices" that the Government challenges as fraudulent. *Id.* (quoting *Ge*, 737 F.3d at 232–33). In other words, it must provide "details that identify particular false claims for payment that were submitted to the government." *Id.* (quoting *Ge*, 737 F.3d at 123). Here, however, the Government does not allege "the existence of an actual false claim," *Guilfoile*, 913 F.3d at 188, related to Defendants' alleged violation of non-discrimination laws. It does not identify the dates, contents, amounts, or recipients of any claims purportedly arising from those regulatory violations. Nor does the Complaint contain individualized allegations linking any supposed discrimination to any claims for payment. That is fatal at the pleading stage. *See Stonebrook*, 2024 WL 1142702, at *1.

The handful of "claims" the Government points to in its complaint do not solve its pleading failure because they do not have anything to do with the alleged discrimination. The Government must allege the "submission of claims ***based on those practices***" that the Government challenges as fraudulent. *Karvelas*, 360 F.3d at 232–33 (emphasis added); *see also Ge*, 737 F.3d at 124 (FCA complaints "must sufficiently establish that false claims were submitted for government payment as a result of the defendant's alleged misconduct" (quotation marks omitted)). But the false "claims" the Government alleges in its complaint concern its AKS theory only (they do not satisfy the Government's burden on that theory for numerous reasons, *supra* pp. 13–36)—not its discrimination theory. The Government alleges these "claims" were related to individuals who "enrolled pursuant to the above-described ***kickbacks***," Compl. ¶¶ 791–98 (emphasis added), not

that they experienced any discrimination. Indeed, under the Government's theory, ***no*** individual for whom a claim was submitted could have experienced discrimination because the alleged discrimination resulted in beneficiaries ***not*** being enrolled and claims ***not*** being submitted.

B. The Government Fails to Plead Falsity.

Even if the Government had identified specific claims implicated by its non-discrimination theories, it still fails to allege that those claims were "false." To allege "falsity" where, as here, the plaintiff relies on an alleged legal violation, the Government must plead that Defendants did not "actually comply[] with" the identified "statute or regulation." *United States ex rel. Westmoreland v. Amgen, Inc.*, 738 F. Supp. 2d 267, 272–73 (D. Mass. 2010); *see also United States ex rel. Crews v. NCS Healthcare of Illinois, Inc.*, 460 F.3d 853, 858 (7th Cir. 2006) (legal-falsity theory cannot succeed if plaintiff "fails to point to a federal regulatory requirement" supporting the theory). Here, the Government identifies two legal provisions—45 C.F.R. Part 92 and 42 C.F.R. § 422.110, Compl. ¶ 819—but fails to allege a violation of either.

45 C.F.R. Part 92. 45 C.F.R. Part 92 implements regulations for § 1557 of the Patient Protection and Affordable Care Act. *See* 42 U.S.C. § 18116. Section 1557, in turn, applies the disability-discrimination provision of Section 504 of the Rehabilitation Act (29 U.S.C. § 794) to certain federal healthcare programs. *Id.* § 18116(a); *see* 45 C.F.R. § 92.207. Part 92 applies the same legal framework applicable to a Section 504 claim in other contexts. *See* 45 C.F.R. § 92.3.[13]

To plead a violation of Section 504, the Government must allege that: (1) a defendant's conduct impacted individuals with a disability; (2) the impacted individuals were otherwise

[13] The portion of the Government's claim premised on 45 C.F.R. Part 92 is limited to the period July 18, 2016 (when the provision came into effect) through August 18, 2020 (when it was repealed). *See Nondiscrimination in Health Programs and Activities*, 81 Fed. Reg. 31,375 (May 18, 2016); *Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority*, 85 Fed. Reg. 37,160 (June 19, 2020). The regulations were reinstated in 2024, after the relevant period covered by this case. *See Nondiscrimination in Health Programs and Activities*, 89 Fed. Reg. 37,522 (May 6, 2024).

qualified to participate in an MA plan; (3) a defendant is a health program or activity which receives federal financial assistance; and (4) the impacted individuals were excluded from participation in, denied the benefits of, or subjected to discrimination solely by reason of their disability. *See J.S.H. v. Newton*, 654 F. Supp. 3d 7, 21 (D. Mass. 2023); *accord Williams v. Massachusetts Coll. of Pharmacy & Allied Health Scis.*, 2013 WL 1308621, at *9 (D. Mass. Mar. 31, 2013). The Government fails to plead the first, second, and fourth elements.

The Government repeats the conclusory assertion that Defendants "were violating applicable statutory, regulatory, and contractual requirements," Compl. ¶ 822, without alleging any factual detail as to the elements of these supposed violations, *see also id.* ¶¶ 823, 847–48, 859. Instead, the Government spends over 150 paragraphs of its Complaint, *see* Compl. ¶¶ 305–77, 484–577, quoting documents in sections with nefarious titles to suggest that Humana and Aetna "discriminate[d] against Medicare beneficiaries with disabilit[ies]," but never identifies a single affected individual, much less any facts about their disability, qualification to participate in MA, or alleged experience of exclusion, denial of benefits, or discrimination.

42 C.F.R. § 422.110. 42 C.F.R. § 422.110 is a separate regulation that provides that MAOs "may not deny, limit, or condition the coverage or furnishing of benefits to individuals eligible to enroll in an MA plan offered by the organization on the basis of any factor that is related to health status, including, but not limited to . . . [d]isability." 42 C.F.R. § 422.110(a). Unlike Part 92, this provision does not expressly link its prohibition to the Section 504 analysis (or to any other analysis for that matter). Regardless, the Government's pleading failure is equally apparent here. Lacking any allegation about a particular individual, their disability, or of the adverse events they allegedly suffered by reason of that disability, the Government cannot plead that any Defendant "den[ied],

limit[ed], or condition[ed] the coverage or furnishing of benefits to individuals eligible to enroll in an MA plan offered by the organization on the basis of . . . [d]isability." *Id.*

C. The Government Fails to Plead Materiality.

The Government also fails to plead that any alleged violations of non-discrimination regulations were "material." As discussed in connection with the Government's AKS-based claim, *supra* p. 26, the Government was required to plead materiality with particularity by, for example, alleging "the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement." *Stonebrook*, 2024 WL 1142702 at *10 (quoting *Escobar*, 579 U.S. at 195). By contrast, the claim cannot survive based on "conclusory allegations as to materiality" that simply assert that the false claims "were material to the U.S. government's decision to purchase." *Id.*; *see also United States v. Fillmore Cap. Partners, LLC*, 2025 WL 971668, at *5 (3d Cir. Apr. 1, 2025) (affirming dismissal of *qui tam* complaint due in part to boilerplate allegations of materiality). Here, the Government fails to plead materiality for at least three reasons.

First, the Government does not offer a single allegation about prior government decisions to refuse payment when faced with similar purported violations. This should come as no surprise, given that the Government's theory is that alleged regulatory violations resulted in claims ***not*** being submitted to the Government; in this situation, there is no claim to pay. *See supra* pp. 37–40. Instead, the Government resorts to boilerplate allegations of materiality that recite Defendants' alleged agreements or certifications of compliance with non-discrimination regulations. Compl. ¶¶ 783–87. But materiality analyzes the effect on "the recipient of the alleged misrepresentation," *Escobar*, 579 U.S. at 193 (quoting 26 R. Lord, Williston on Contracts § 69:12, p. 549 (4th ed. 2003)), which is the Government, *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 491 (3d Cir. 2017). Allegations about what Defendants said or did have nothing to do with how

the Government has acted when faced with similar alleged noncompliance in the past. Nor does merely reciting that the provisions are, in the Government's view, "material" move the needle. That is precisely the type of "conclusory allegation[] as to materiality" that is rejected as a matter of course. *Stonebrook*, 2024 WL 1142702, at *10; *see also supra* pp. 26–31.

The Government could not possibly plead materiality here. CMS has well-established tools to enforce compliance with § 422.110 and with 45 C.F.R. Part 92 independent of the FCA. *See* 42 C.F.R. § 422.752(a)(4) (applying CMS intermediate sanctions and monetary penalties authority to "any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by this part) by eligible individuals with the organization whose medical condition or history indicates a need for substantial future medical services"). Yet it has never invoked or used those tools here. *See D'Agostino*, 845 F.3d at 8 (observing that the FCA is not a vehicle for "second-guess[ing] agencies' judgments").

Second, the Government does not plead that the alleged non-discrimination violations go to the "essence of the bargain" between Defendants and CMS. This factor looks to the "impact" the alleged falsehood had "on the goals of the contract." *Bonzani*, 662 F. Supp. 3d at 232 (quoting *Yu, LLC*, 2022 WL 7785044, at *4); *see also Foreman*, 19 F.4th at 117 (violation insubstantial where the alleged falsity "do[es] not necessarily undermine the . . . Contract's core purpose"). Alleged violations of Medicare requirements are insubstantial where the defendant provided the government exactly what it paid for. *See, e.g.*, *Spay*, 875 F.3d at 764 (violation not material where "[t]he government did not pay for services that were not provided"); *Mbabazi*, 2021 WL 4453600, at *6 (violation not material in managed care case, where there was no allegation the false claim affected the capitated rate of reimbursement paid by CMS, because "there is no FCA liability

where a falsely-claimed service or item does not affect the rate of reimbursement") (quoting *United States v. Kindred Healthcare, Inc.*, 469 F. Supp. 3d 431, 445 (E.D. Pa. 2020)).

Accepting the allegations in the Complaint as true, the Government here received precisely what it paid for. The MAO Defendants provided (or, in the case of the TPMO Defendants, provided marketing and enrollment services relating to) MA insurance coverage to qualified individuals. The Government does not allege that it paid for MA insurance coverage that was not provided or that the coverage provided was deficient in any way or that any beneficiary who was not eligible for enrollment was enrolled. At most, the Government alleges that a separate, small slice of the Medicare-eligible population was marketed to in a way that made those individuals less likely to enroll in one of Defendants' plans (and as a result, the Government did ***not*** pay any money to any MAO Defendant for their coverage).

Third, compliance with the non-discrimination regulations is not a "condition of payment" and, even if it was, that would not be sufficient to establish materiality. *Escobar*, 579 U.S. at 178. The non-discrimination provisions are not conditions of payment, which would require "express and absolute language" stating that payment is conditioned on compliance with the regulation or statute. *United States ex rel. Escobar v. Universal Health Servs., Inc.*, 780 F.3d 504, 514 (1st Cir. 2015), *vacated and remanded*, 579 U.S. 176 (2016);[14] *see also United States ex rel. Yu v. Grifols USA, LLC*, 2021 WL 5827047, at *8 (S.D.N.Y. Dec. 8, 2021) (payment condition must be "express"). 42 C.F.R. § 422.110, in contrast, simply prohibits MAOs from refusing to cover individuals or placing limitations on their coverage based on certain enumerated factors. Similarly, 45 C.F.R. 92.101(a) enacts a general prohibition on discrimination in connection with health

[14] The provision in question in *Escobar* stated that the relevant services were "reimbursable only if the program meets the" regulatory standards at issue there. *Id.* at 511.

benefits. Neither 42 C.F.R. § 422.110 nor 45 C.F.R. § 92.101(a) includes "express" language conditioning payment on compliance.

Nor can the Government rely on a catchall regulation stating that a list of more than 20 contractual "requirements and conditions" are all "material to the performance of" all contracts between MAOs and CMS. 42 C.F.R. § 422.504(a); *see* Compl. ¶ 769. As discussed in connection with the Government's AKS claim, *supra* pp. 26–31, such an argument has been squarely rejected in prior cases and is foreclosed by the Supreme Court's decision in *Escobar*.

D. The Government Fails to Plead Causation of Any False Claim for Payment or Resulting Loss.

The Government also fails to plead facts establishing the requisite causal link between Defendants' alleged false certifications and any loss to the Government. That is because the Government indisputably suffered no loss from the alleged discrimination. To the contrary, as previously noted, the Government's theory is that Defendants' conduct resulted in the Government ***not*** paying money it otherwise would have paid because that conduct allegedly resulted in MAO Defendants ***not*** enrolling certain beneficiaries that the Government argues should have been enrolled, and therefore ***not*** making resulting claims for capitated payments for such beneficiaries. That is not a viable theory of FCA liability as a matter of law.

There can be no FCA liability if allegedly wrongful conduct does not cause the submission of a claim for payment. *Karvelas*, 360 F.3d at 225 ("Evidence of an actual false claim is the sine qua non of [an FCA] violation") (quotations omitted); *Vargas*, 134 F.4th at 1157 ("The FCA targets false claims—not regulatory violations, not internal misconduct, and not abstract theories untethered from government payment . . . . [s]o to state a viable FCA claim, a relator must allege not just a scheme, but a scheme that actually led to false claims being submitted to the government—and he must do so with particularity.") (citations omitted). Numerous courts of

appeals have taken this a step further, listing a resulting Government ***payout or other loss*** among the required elements of a viable FCA claim.[15] Those decisions comport with the FCA's language providing that the Government can recover as damages only losses it "sustains ***because of*** the [allegedly unlawful] act." 31 U.S.C. § 3729(a)(1) (emphasis added). This all flows naturally from the fact that the FCA incorporates "elements of common-law fraud that are consistent with the statutory text." *Escobar*, 579 U.S. at 187 n.2. Causation of loss (a/k/a detrimental reliance), of course, is a required element of any common law fraud claim. *See, e.g.*, *Gattineri v. Wynn MA, LLC*, 63 F.4th 71, 87–88 (1st Cir. 2023); *Paraflon Investments, Ltd. v. Fullbridge, Inc.*, 960 F.3d 17, 24–25 (1st Cir. 2020). And "but for" cause is necessary but not sufficient; the Government also must establish proximate cause. *Urquilla-Diaz*, 780 F.3d at 1052; *see also, e.g.*, *Petratos*, 855 F.3d at 491 (causation element "cannot be met merely by showing 'but for' causation").

Regardless of how the Court articulates these required elements, however, there simply is no circumstance in which an alleged scheme that, by all accounts, does ***not*** result in any claim for

[15] *See, e.g.*, *United States v. Atlanta Primary Care Peachtree, PC*, 2025 WL 1823269, at *4 (11th Cir. July 2, 2025) ("[W]hen a relator brings a false statement claim, she must allege with particularity that the defendant's false statements ultimately led the government to pay amounts it did not owe.") (cleaned up) (citation omitted); *United States v. Care Alternatives*, 81 F.4th 361, 366–67 (3d Cir. 2023) (requiring, as an element of an FCA claim, that the defendant "caus[ed] the government to make a payment"); *United States v. Corp. Mgmt., Inc.*, 78 F.4th 727, 737 (5th Cir. 2023) (requiring, as an element of an FCA claim, that the defendant "caused the government to pay out money or to forfeit moneys due"), *cert. denied*, 144 S. Ct. 694 (2024); *United States v. Walgreen Co.*, 78 F.4th 87, 92 (4th Cir. 2023) (same); *United States v. Molina Healthcare of Illinois, Inc.*, 17 F.4th 732, 740 (7th Cir. 2021) ("The plaintiff also must prove that the [false statement] proximately caused the alleged injury."); *Ruckh v. Salus Rehab., LLC*, 963 F.3d 1089, 1103 (11th Cir. 2020) (including among the elements of a false certification theory of liability that the false or fraudulent conduct "caus[ed] . . . the government to pay out money or forfeit moneys due") (quoting *Urquilla-Diaz*, 780 F.3d at 1045); *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266 (9th Cir. 1996) (discussing the need for the alleged false certification to have "caused the United States to provide an improper benefit"); *but see United States v. Rivera*, 55 F.3d 703, 709 (1st Cir. 1995) (noting that a defendant who "submits a false claim for payment may still be liable under the FCA for statutory penalties, even if it did not actually induce the government to pay out funds or to suffer any loss," but maintaining that liability only attaches to an actual "claim for payment").

payment, can violate the FCA.[16] But that is precisely what the Government alleges in Counts III, V, and VII: a purported disability discrimination scheme that—taken on the Government's own terms—caused no claims for payment or Government financial loss. None of the allegedly "false claims" the Government highlights elsewhere in its Complaint (¶¶ 791–98) has any alleged connection to purported discrimination; the Government characterizes them all as related to "the above-described ***kickbacks***." *See id.* (emphasis added). Nothing in Defendants' alleged certifications or marketing activities that supposedly served to steer disabled beneficiaries to other MA plans or otherwise discriminate against disabled beneficiaries had ***any*** causal connection—but-for, proximate, or otherwise—to the submission of any claim or the Government losing any money. *See United States ex rel. Silva-Ramirez v. Hospital Espanol Auxilio Mutuo De Puerto Rico, Inc.*, 2018 WL 11339417, at *1 (1st Cir. Mar. 30, 2018) (affirming dismissal of FCA claims related to purported religious discrimination because "[t]he connection between the falsehoods alleged and the payments received" was "exceedingly attenuated, and falls well short of the plausibility requisite to federal pleading") (quotations omitted).

E. The Government Fails to Plead Damages.

Even if the Government had pled the elements of its discrimination theory, it failed to plead a viable theory of damages. Its request for those remedies therefore should be dismissed. *See United States ex rel. Davis v. D.C.*, 679 F.3d 832, 840 (D.C. Cir. 2012) (upholding dismissal of damages remedy where allegations made clear "the government suffered no damages").

[16] While the *Flanagan* and *Regeneron* decisions discussed above, *see, e.g.*, *supra* pp. 31–37, both made reference to false certification FCA theories not requiring proof of causation, neither suggested (much less held) that a false certification in the ***absence*** of a related claim for payment could result in FCA liability. As the *Flanagan* court aptly put it, "with respect to the overarching kickback scheme, he still must plead with particularity ***the connection between*** false records and/or statements and the intent to have a false claim paid for by the government programs." 142 F.4th at 37 (emphasis added) (citing *United States ex rel. Gagne v. City of Worcester*, 565 F.3d 40, 46 (1st Cir. 2009)).

Damages under the FCA require "not only that the defendant's false claims caused the government to make payments that it would have otherwise withheld, but also that the performance the government received was worth less than what it believed it had purchased." *United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1279 (D.C. Cir. 2010). "In most FCA cases, damages are measured as they would be in a run-of-the-mine breach-of-contract case—using a 'benefit-of-the-bargain' calculation in which a determination is made of the difference between the value that the government received and the amount that it paid." *United States ex rel. Concilio De Salud Integral De Loíza, Inc. v. J.C. Remodeling, Inc.*, 962 F.3d 34, 42 (1st Cir. 2020) (quoting *United States v. Foster Wheeler Corp.*, 447 F.2d 100, 102 (2d Cir. 1971)). This measure compares the market value of the services the Government was promised to the market value of the services actually delivered. *See United States v. Bornstein*, 423 U.S. 303, 316 n.13 (1976).

The Government's allegations here make clear that it received exactly what it paid for: insurance coverage for eligible enrollees. It does not allege that any enrolled beneficiary lacked coverage, received inferior medical services, or was ineligible under the MA plans CMS approved and funded. Nor does the Complaint allege CMS would not have covered the individuals who ***were*** enrolled by Defendants absent the alleged non-discrimination violations. *Cf. Davis*, 679 F.3d at 840 (the alleged "defect in this case in no way calls into question the value of the medical care provided"). Nor does the Government allege it suffered any quantifiable loss from the alleged ***non***-enrollment of other individuals as a result of discrimination. *See supra* pp. 37–40, 45–47.

III. THE GOVERNMENT FAILS TO PLEAD CONSPIRACY CLAIMS.

The Complaint also alleges FCA conspiracies related to the Government's AKS theory (Count VI) and its non-discrimination theory (Count VII). Compl. ¶¶ 854, 859. Those claims are based on the same theories that fail for the reasons set forth above, *supra* pp. 13–48. *See United States ex rel. Hagerty v. Cyberonics, Inc.*, 95 F. Supp. 3d 240, 269 (D. Mass. 2015), *aff'd sub nom.*

Hagerty ex rel. United States v. Cyberonics, Inc., 844 F.3d 26 (1st Cir. 2016) (dismissing an FCA conspiracy claim, in part, "[b]ecause the complaint does not state allegations of fraud under the FCA with the particularity required by Rule 9(b)"); *United States ex rel. Kasowitz Benson Torres LLP v. BASF Corp.*, 929 F.3d 721, 728 (D.C. Cir. 2019) (to prevail on FCA conspiracy count, the relator "had to establish an underlying FCA violation" but failed to do so).

Moreover, "[i]t is not enough for [the Government] to show there was an agreement that made it *likely* there would be a violation of the FCA; [it] must show an agreement was made *in order to* violate the FCA." *United States ex rel. Michigan v. State Farm Mut. Auto. Ins. Co.*, 2025 WL 101639, at *4 (6th Cir. Jan. 15, 2025) (emphasis in original) (quoting *United States ex rel. Ibanez v. Bristol-Myers Squibb Co.*, 874 F.3d 905, 917 (6th Cir. 2017)); *see also United States ex rel. Nicholson v. MedCom Carolinas, Inc.*, 42 F.4th 185, 193 (4th Cir. 2022) (plaintiff alleging FCA conspiracy "must show that the defendants 'agreed that [a] false record or statement would have a material effect on the Government's decision to pay [a] false or fraudulent claim") (quoting *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 673 (2008)). The Government's factual allegations make no such showing here.

The conspiracy claims also fail because an FCA conspiracy claim "cannot survive a motion to dismiss" where the Government fails to "allege any facts as to: (1) who the co-conspirators are, (2) when or where they entered into an agreement, or (3) what overt acts they took in furtherance of the conspiracy." *United States ex rel. Leysock v. Forest Lab'ys, Inc.*, 55 F. Supp. 3d 210, 221 (D. Mass. 2014); *see also State Farm*, 2025 WL 101639, at *4 ("[R]elators must allege who was [a] party to the agreement, how the agreement was reached, when the agreement was reached, and what were its terms.") (quoting *United States ex rel. Angelo v. Allstate Ins. Co.*, 106 F.4th 441, 452 (6th Cir. 2024), *cert. denied*, 145 S. Ct. 550 (2024)); *Gagne*, 565 F.3d at 45 (FCA conspiracy

claims must be pled with particularity and conclusory allegations are insufficient). Once again, the Government has not done that. Here, the Government makes only a conclusory allegation, as to both Counts VI and VII, that Defendants "violated 31 U.S.C. § 3729(a)(1)(C) by conspiring together and with known and unknown individuals." Compl. at ¶¶ 854, 859. The Government does not identify those individuals, plead anything about any specific agreement Defendants allegedly entered into with those individuals, or say what overt acts they took in furtherance of the agreement or agreements. That "bare legal conclusion" of conspiracy, "unsupported by specific allegations of any agreement or overt act," is insufficient to state a claim for FCA conspiracy. *Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1014 (11th Cir. 2005); *see also, e.g.*, *Angelo*, 106 F.4th at 453 (affirming dismissal of FCA conspiracy claim).

Nor can the Government rely on its general allegations about the existence of contracts between individual MAO and TPMO Defendants. *See, e.g.*, Compl. ¶¶ 106, 384, 580.[17] Separate, arms-length contracts among various MAO and TPMO pairs—competitors in the same market—do nothing to plead a single over-arching conspiracy. *See United States v. Select Rehabilitation Inc.*, 696 F. Supp. 3d 48, 62 (E.D. Pa. 2023) ("Absent allegations suggesting a unity of purpose, a common design and understanding, or a meeting of the minds between and among the spokes, the plaintiff cannot establish the existence of a single conspiracy linking all the defendants."). Nor do those arms-length contracts supply a basis for finding multiple conspiracies each comprised of a single Defendant MAO and a single Defendant TPMO, as the Government alleges nothing to support the inference that they constitute "an agreement . . . ***to defraud the government***." *United*

[17] The Government does not allege that there were any marketing contracts between Elevance Health and SelectQuote or that there otherwise was any relationship between these two defendants. That pleading failure independently requires dismissal of a conspiracy between these Defendants.

States ex rel. Est. of Cunningham v. Millennium Lab'ys of Cal., 2014 WL 309374, at *2 (D. Mass. Jan. 27, 2014) (emphasis added).

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

The Government tacks on a federal-law claim for "unjust enrichment." Compl. ¶¶ 862–66. Because "[t]here is no federal general common law," *Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938), the Court should not recognize a federal common law unjust enrichment claim. The Court need not reach that issue, however, because it can—as courts often do—dismiss an unjust-enrichment claim appended to an FCA claim because the FCA confers an adequate remedy at law. *See, e.g.*, *Teva Pharms*, 560 F. Supp. 3d at 423–24; *United States ex rel. Martino-Fleming v. South Bay Mental Health Ctrs.*, 540 F. Supp. 3d 103, 133 (D. Mass. 2021); *see also Am. Elec. Power Co. v. Connecticut*, 564 U.S. 410, 423 (2011) ("[W]hen Congress addresses a question previously governed by a decision rested on federal common law, . . . the need for such an unusual exercise of law-making by federal courts disappears.") (quoting *Milwaukee v. Illinois*, 451 U.S. 304, 314 (1981)). That is particularly appropriate here, as the Government alleges that there are contracts that govern the issues in dispute. *See* Compl. ¶¶ 39, 92–97, 113, 305, 484, 767–74, 776, 783–87, 806–07, 809, 819, 821, 830–31, 833, 842, 846, 855, 859; *see Hebert v. Vantage Travel Serv.*, 444 F. Supp. 3d 233, 245 (D. Mass. 2020) ("Unjust enrichment . . . is a doctrine of quasi-contract that does not apply where an actual contract controls . . . .").

Even if an unjust enrichment claim could be brought here, the Government has not pleaded it. Unjust enrichment generally requires that it would be inequitable for a defendant to accept or retain a benefit. *E.g.*, *Herbert*, 444 F. Supp. 3d at 245. The Government's AKS-based claims fail to plead that Defendants received improper payments, *see supra* pp. 13–16, 21–25, and the discrimination-based claims actively plead that Defendants' conduct led to them ***not*** obtaining payments, *see supra* pp. 37–48.

At minimum, the Court should strike the Government's demand for a jury trial on its unjust enrichment claim. *See* Compl. at p. 213. Jury trials attach to claims at ***law***, not equity. *See, e.g.*, *Braunstein v. McCabe*, 571 F.3d 108, 117 (1st Cir. 2009) (quoting *Granfinanciera, S.A. v. Nordberg*, 492 U.S. 33, 41 (1989)). The Government's unjust-enrichment claim, as well as the relief it seeks for it, are plainly equitable. *See* Compl. ¶¶ 864–65 (using the word "equity" twice in the six paragraphs of allegations about the unjust enrichment claim); *Great-West Life & Annuity Ins. Co. v. Knudson*, 534 U.S. 204, 214 (2002) (return of particular funds is an equitable remedy); *Brown v. Sandimo Materials*, 250 F.3d 120, 126 (2d Cir. 2001) (same).

CONCLUSION

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

Dated: August 19, 2025

Respectfully submitted,

/s/ Zachary R. Hafer
Zachary R. Hafer (BBO #569389)
Adam M. Katz (BBO #706834)
Isabel C. McGrath (BBO #712925)
SIMPSON THACHER & BARTLETT LLP
855 Boylston Street
Boston, MA 02116
Telephone: (617) 778-9200
zachary.hafer@stblaw.com
adam.katz@stblaw.com
isabel.mcgrath@stblaw.com
Counsel to eHealth, Inc. and eHealthInsurance Services, Inc.

/s/ Holly M. Conley
Enu Mainigi (*pro hac vice*)
Kenneth Brown (*pro hac vice* pending)
Holly M. Conley (*pro hac vice*)
Benjamin Hazelwood (*pro hac vice* pending)
Jeffrey G. Ho (BBO #714047)
WILLIAMS & CONNOLLY LLP
680 Maine Avenue SW
Washington, DC 20024
Telephone: (202) 434-5000
emainigi@wc.com
kbrown@wc.com
hconley@wc.com
bhazelwood@wc.com
jho@wc.com
Counsel to CVS Health Corporation, Aetna Life Insurance Company, and Aetna Inc.

/s/ Richard Westling
Richard Westling (*pro hac vice*)
PROSKAUER ROSE, LP
1001 Pennsylvania Ave., NW, Suite 600 South
Washington, DC 20004
Telephone: (202) 416-5876
rwestling@proskauer.com
Counsel to SelectQuote, Inc.

/s/ Erik W. Weibust
Erik W. Weibust (BBO #663270)
Clay Lee (*pro hac vice*)
EPSTEIN BECKER & GREEN PC
One Financial Center, Suite 1520
Boston, MA 02111
Telephone: (617) 603-1090
eweibust@ebglaw.com
clee@ebglaw.com
Counsel to SelectQuote, Inc.

/s/ Kelly H. Hibbert
Kelly H. Hibbert (*pro hac vice*)
Michael Shaheen (*pro hac vice*)
Troy Barsky (*pro hac vice*)
Payal Nanavati (*pro hac vice*)
Lauren J.R. Nunez (BBO #687390)
CROWELL & MORING LLP
1001 Pennsylvania Ave., NW
Washington, DC 20004
Telephone: (202) 624-2500
khibbert@crowell.com
mshaheen@crowell.com
tbarsky@crowell.com
pnanavati@crowell.com
lnunez@crowell.com
Counsel to Humana Inc.

/s/ Laura McLane
Laura McLane (BBO #644573)
David Gacioch (BBO #660784)
Mara Theophila (BBO #704763)
Natasha Dobrott (BBO #705287)
MCDERMOTT WILL & SCHULTE LLP
200 Clarendon Street, 58th Floor
Boston, MA 02116
Telephone: (617) 535-4410
lmclane@mwe.com
dgacioch@mwe.com
mtheophila@mwe.com
ndobrott@mwe.com
Counsel to GoHealth, Inc.

/s/ Lisa M. Noller
Lisa M. Noller (*pro hac vice*)
Patrick J. McMahon (*pro hac vice*)
Jamie Steven (BBO #705904)
FOLEY & LARDNER LLP
321 North Clark Street, Suite 3000
Chicago, Illinois 60654
Telephone: (312) 832-4500
lnoller@foley.com
pmcmahon@foley.com
Counsel to Elevance Health, Inc.

CERTIFICATE OF COMPLIANCE WITH LOCAL RULE 7.1

Pursuant to Local Rule 7.1(a)(2), I hereby certify that counsel for Defendants conferred in good faith with counsel for the Government regarding the foregoing motion in an effort to resolve or narrow the issues contained therein.

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

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 August 19, 2025.

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