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A Major New FCA Action, the DOJ's 2025 'National Health Care Fraud Takedown,' and the First Appellate Court Decision Interpreting EKRA

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he prior edition of this Healthcare Enforcement column briefly mentioned a new and significant False Claims Act (FCA) lawsuit in which the government alleges that major health insurers and brokers paid for beneficiaries to be referred to the insurers' Medicare Advantage Plans, and that the same FCA defendants also allegedly discriminated against disabled beneficiaries.

This issue of the column expands upon the discussion of that ongoing FCA matter, and then turns to two other recent developments: the Department of Justice's (DOJ) "2025 National Health Care Fraud Takedown," in which DOJ announced criminal charges against more than 300 defendants across the country; and a decision in which, for the first time, a federal appeals court addressed the reach of the Eliminating Kickbacks in Recovery Act (EKRA).

The Government's FCA Lawsuit Alleging Kickbacks and Discrimination in Connection with Medicare Advantage Plans

Since assuming office, the current administration has been unambiguous about its intent to pursue fraud and abuse in the Medicare Advantage program (also known as Medicare Part C), by which Medicare-eligible individuals receive benefits through private health care plans.

At a February. 2025 conference, DOJ officials discussed the agency's focus on Medicare Advantage and noted that the large health care expenditures occurring through the program make it a prime target

for fraud.

In May 2025, the Centers for Medicare and Medicaid Services announced a plan to "enhance and accelerate Medicare Advantage audits" in order to "crush[] fraud, waste and abuse."

More recently, in late July 2025, United Healthcare acknowledged that it was



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responding to civil and criminal requests regarding its Medicare business, and news reports have suggested that the government's investigation relates to the company's Medicare Advantage plans.

Consistent with this intensified government focus on Medicare Advantage is *United States ex rel. Shea v. eHealth, Inc. et al.,* 21-cv-11777 (DJC) (D. Mass.), an FCA case in which the DOJ recently filed a complaint in partial intervention against major health insurers and brokers involved in Medicare Part C.

Broadly speaking, the government's allegations in the *eHealth* complaint fall into two main categories.

First, the government alleges that from 2016 through at least 2021, three insurance company defendants (Aetna, Humana, and the former Anthem, now known as Elevance) paid kickbacks to three insurance brokers (eHealth, GoHealth, and SelectQuote) so that the brokers would steer Medicare beneficiaries to the insurers' Medicare Advantage plans.

According to the government's complaint, the insurers paid "hundreds of millions of dollars" to the brokers pursuant to "sham" contracts and invoices that purported to be for marketing or administrative services.

In turn, the brokers allegedly directed Medicare beneficiaries to the plans "offered by insurers that paid them the most money," without regard to whether those plans were in the beneficiaries' best interests.

Based largely on these assertions, the complaint asserts that the defendants violated the Anti-Kickback Statute (AKS); submitted claims that were the result of such AKS violations; falsely represented their compliance with applicable statutes, regulations, and contracts; and thereby violated, and conspired to violate, the FCA.

Second, the government alleges in its complaint that two of the insurers—Aetna and Humana—used the above-described kickbacks not only to increase enrollment, but also to cause the defendant brokers to discriminate against disabled beneficiaries by limiting the number of those beneficiaries who enrolled in the Aetna and Humana plans.

According to the complaint, because Aetna and Humana allegedly "perceived [disabled beneficiaries] as more expensive to cover," and because of the "financial inducements" that Aetna and Humana were allegedly paying, the defendant brokers "rejected referrals of disabled beneficiaries, filtered telephone calls from disabled beneficiaries, and strategically directed disabled beneficiaries away from Aetna and Humana plans."

Based on these allegations, the government's complaint asserts that Aetna, Humana, and the insurance broker defendants committed a separate set of FCA violations arising from, among other things, false certifications of compliance with non-discrimination requirements in beneficiary enrollment

The government's intervention in the *eHealth* litigation occurred just slightly over two months ago, and so the future of the matter, including whether the government will be able to establish its claims, remains to be seen.

However, a recent filing by certain of the defendants provides some sense of what to anticipate, and what arguments to look for.

On July 30, 2025, the defendant brokers, together with Humana and WellCare (the latter of which is not currently named in the government's complaint,

but is still apparently the subject of ongoing FCA investigation) filed an unopposed motion to stay all proceedings relating to the relator's underlying *qui tam* complaint.

In arguing that the interests of efficiency and consistent outcomes would be served by staying proceedings involving the *qui tam* complaint, the moving defendants pointed towards two future developments.

First, the defendants stated their intent to move to dismiss the government's complaint in its entirety (albeit on grounds that the defendants have not yet identified).

Second, the moving defendants noted that, without a stay, the district court would need "to decide constitutional and statutory issues regarding the Relator's ability—or lack thereof—to proceed on non-intervened claims."

In other words, the motion plainly suggests (and in fact, explicitly asserts through case citations included in a footnote) that the defendants in *eHealth*, like a growing number of FCA defendants, will challenge the *qui tam* provision of the FCA on constitutional appointments clause grounds.

DOJ's '2025 National Health Care Fraud Takedown'

On June 30, 2025, the Trump administration's DOJ issued a press release and conducted a press conference to announce the results of its "2025 National Health Care Fraud Takedown."

Although the Biden administration had made similar announcements each year from 2021 to 2024 as part of its "Nationwide Health Care Fraud Enforcement Actions," the current DOJ described its 2025 Takedown as the "largest Justice Department health care fraud takedown in history," with more than \$14.6 billion in intended loss.

The 2025 Takedown is undoubtedly extensive in scope, as it included criminal charges against 324 defendants in 50 federal districts and the courts of 12 states; involved the coordinated actions of numerous federal and state law enforcement agencies; and resulted in the arrest of 96 medical professionals.

Nonetheless, before attempting to identify any takeaways that can be drawn from the 2025 Takedown, it may first be helpful to clarify a matter of terminology.

In common law enforcement parlance, and likely in the public perception as well, a "takedown" refers to an operation by which, on a specific day, law enforcement agents utilize the benefit of surprise to sweep through a specific group of co-conspirators or a given geographic area for maximum impact, often in order to disrupt the organization's activities and arrest as many individuals as possible before others learn of the arrests and can flee, destroy evidence, or otherwise impede law enforcement efforts.

However, rather than constituting a coordinated series of arrests occurring on the same day or close in time, the 2025 Takedown instead reflected DOJ's identification of a range of health care-related cases from a broad time period, and its decision to group them together under the banner of a "takedown."

For example, among the first 15 indictments and criminal informations to which DOJ provided links as part of its press materials for the 2025 Takedown, there are charging instruments that were publicly filed in March and April 2025 (two to three months before the "Takedown" itself), as well as charging instruments from August, September, and November 2024 (none of which were initiated by the present administration).

Additionally, whereas a takedown is typically understood to include the arrest of a group of defendants without warning, the cases included in the 2025 Takedown involved at least one matter—*United States v. Nakhmatullaev, et al.*, 25-cr-203 (RPK) (E.D.N.Y.), which charges alleged members of a transnational criminal organization with health care fraud and money laundering—where the unsealed indictment and the government's press release took the unusual step of publicly identifying individuals who are outside of the United States, have not been arrested, and can therefore alter their conduct to avoid being "taken down" in the first place.

In any event, whether or not the 2025 Takedown falls within the commonly understood definition of that term, and despite the fact that the 2025 Takedown includes cases commenced by the prior presidential administration, the types of cases included in the DOJ's announcement can still serve to identify the health care enforcement priorities of the current administration.

In this regard, although the types of cases included in the Takedown are wide ranging in nature and not remarkably different from cases pursued by the Biden administration, the DOJ's press release specifically emphasizes the government's focus on schemes involving international criminal organizations, fraudulent wound care, prescription opioid trafficking, and telemedicine and genetic testing fraud.

Further, although the DOJ has long used claims data to identify anomalous billing patterns and target possible fraud, the DOJ's media materials from the Takedown also announced the creation of a "Health Care Fraud Data Fusion Center," by which law enforcement experts from various agencies can "leverage cloud computing, artificial intelligence, and advanced analytics to identify emerging health care fraud schemes."

Finally, regardless of whether the 2025 Takedown necessarily paves previously untrodden ground in the realm of health care enforcement, the extensive list of case descriptions in the government's media materials will undoubtedly have value as a searchable resource for practitioners seeking out cases similar to those they may be defending, and also may provide a persuasive means to educate health care clients about the potential risks of contemplated conduct.

Ninth Circuit Provides Guidance on Whether EKRA Reaches Payments Made to Marketing Intermediaries

The third and final matter discussed in this column is *United States v. Schena*, 142 F.4th 1217 (9th Cir. 2025). The Ninth Circuit issued its *Schena* decision on July 11, 2025, and the decision constitutes the first appellate court interpretation of the Eliminating Kickbacks in Recovery Act (EKRA), 18 U.S.C. §220, which prohibits remuneration for referrals to recovery homes, clinical treatment facilities, or laboratories.

The decision in *Schena* arose from the government's indictment of medical testing laboratory operator Mark Schena, whom the government alleged had made payments to marketing intermediaries to induce referrals for allergy tests processed by his lab, Arrayit.

The government alleged that Schena tasked the Arrayit marketers with convincing less sophisticated doctors (those who were not allergists, for example) that Arrayit's blood test for allergies was superior to skin tests, even though aspects of the Arrayit tests were often unnecessary, were disfavored by allergists, and were subject to limitations that undercut their utility.

Further, when the volume of allergy testing fell during the COVID-19 pandemic, Schena allegedly used marketing agents to sell Arrayit's COVID blood test, which tested for antibodies rather than the active infections detected by "gold standard" PCR tests.

Schena also allegedly directed marketers to induce the bundling of allergy tests with COVID tests, and to induce the testing of more allergens than were necessary, in return for the marketers receiving a percentage of the revenue they brought in.

Following a trial in the Northern District of California, a jury convicted Schena of, among other offenses, two counts of violating EKRA, and he was sentenced to 96 months in prison and required to pay over \$24 million in restitution.

On appeal, defendant Schena and the government focused on two primary arguments: (1) whether EKRA extends broadly enough to proscribe marketing intermediary relationships in which a defendant pays marketing agents to induce referrals by medical professionals, as opposed to proscribing only payments made to those persons who interact directly with patients or do the actual patient referring; and (2) what the statutory phrase "to induce a referral" means in the context of an intermediary marketing agent relationship.

On the first of these questions, the Ninth Circuit rejected an earlier district court decision from the District of Hawaii and held that EKRA prohibited the payments Schena had made to his marketing agents, despite the fact that the agents did not themselves order the tests and never interfaced with patients.

Based on a plain reading of the statute's text, the Ninth Circuit found that EKRA does not require the recipient of an unlawful payment to have the ability to order a laboratory test, refer a patient to a treatment facility, or even interact with patients.

The court noted that there is no such explicit requirement in the statute, and that the statute's language prohibiting payments that are made "directly or indirectly" undercut Schena's argument that payments to marketing agents were outside the statute's reach.

Relying on other circuits' interpretations of an analogous provision of the AKS, the Ninth Circuit also reasoned that if EKRA's reach were limited to only those situations in which payments were made to actual referrers, then those involved in payment-for-referral schemes could evade EKRA simply by having medical professionals enlist office managers or other subordinates to pressure patients into using the provider's services.

Turning next to the meaning of the term "induce," the Ninth Circuit once again looked to decisions interpreting

the AKS and concluded that, as in the AKS, the term "induce" in EKRA does not reach every effort to encourage or influence the judgment of medical professionals.

Instead, the Ninth Circuit held that for the "inducement" element of EKRA to be satisfied, there must be a "wrongful effort to unduly influence the decisions of doctors and medical professionals making referrals."

Against this backdrop, the Ninth Circuit found that while percentage-based compensation structures for marketing agents are not *per se* violations of EKRA, if a defendant pays remuneration to a marketer for the purpose of unduly influencing doctors' referrals through false or fraudulent representations about the services, such payments constitute an EKRA violation.

Applying this standard to the facts of the case, the court found that the trial evidence was sufficient to establish undue influence, because a jury could have reasonably found that Schena directed marketers to mislead and deceive doctors into making referrals to his lab.

Notably, the Ninth Circuit acknowledged that the circumstances presented in *Schena* were not the only way in which payments to marketing intermediaries may reflect a wrongful effort to unduly influence the decisions of medical professionals in violation of EKRA, and that future cases will be needed to flesh out the bounds of the statute.

Also noteworthy, given that *Schena* is binding only in the Ninth Circuit and the bounds of EKRA have not yet crystallized, is the Ninth Circuit's identification in *Schena* of one way by which companies and marketing agents can "steer clear" of EKRA violations—namely, by structuring the compensation of marketing agents in accordance with the statute's safe harbor provision at 18 U.S.C. §220 (b) (2), so that payments do not vary based on the number of referrals made, the number of tests or procedures performed, or the amount billed to or received from health care benefit programs.

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