AHLA

# Journal of Health & Life Sciences Law

VOLUME 13, NUMBER 2 | FEBRUARY 2020

## FEATURED ARTICLES



## PRACTICE RESOURCES



OFFICIAL JOURNAL OF AMERICAN HEALTH LAWYERS ASSOCIATION

Practice Resource

# Beyond the False Claims Act: The Government's Untraditional Tools in Health Care Fraud Prosecutions

A. Lee Bentley III and Jason P. Mehta

**ABSTRACT:** This article explores the Department of Justice's (DOJ) role in health care enforcement. The article specifically tracks both traditional and more novel statutes that DOJ is using to prosecute its cases, including a discussion of the Department's use of the Travel Act, the Racketeering Influenced and Corrupt Organizations Act (RICO), and the Eliminating Kickbacks in Recovery Act (EKRA) statute. In doing so, the article explains the elements of these statutes and highlights several recent case examples. The article concludes with several practical considerations for health care practitioners and those who advise practitioners.

A. Lee Bentley III & Jason P. Mehta, *Beyond the False Claims Act: The Government's Untraditional Tools in Health Care Fraud Prosecutions*, J. Health & Life Sci. L., Feb. 2020, at 90.

# Beyond the False Claims Act: Untraditional Tools in Fraud Prosecutions

## ARTICLE CONTENTS

## INTRODUCTION

In one of his last speeches as Attorney General of the United States, Jeff Sessions proudly boasted: "We are sending a clear message to criminals across the country: we will find you. We will bring you to justice. And you will pay a very high price for what you have done."[1] This type of rhetoric is often reserved for serious criminal offenders. What was notable about these remarks, however, was that Attorney General Sessions was directing these comments to a particular class of individuals—health care providers.

It is obvious to even casual observers that the Department of Justice (DOJ) is focused on health care fraud. Seemingly by the month, DOJ announces new record-breaking criminal and civil enforcement efforts.[2] What might be less obvious, however, is that DOJ is increasingly digging ever deeper into its arsenal of tools to prosecute health care offenses. While DOJ continues to bring cases rooted in the False Claims Act and typical criminal health care fraud, prosecutors are starting to use new statutes and tools to tackle an array of schemes.

This article explores several of the traditional and more novel statutes that DOJ is using to prosecute its cases, including a discussion of the Department's use of the Travel Act, the Racketeering Influenced and Corrupt Organizations Act (RICO), and the Eliminating Kickbacks in Recovery Act (EKRA) statute. In doing so, the article explains the elements of these statutes and highlights several recent case examples. The article concludes with several practical considerations for health care practitioners and those who advise practitioners.

## TRADITIONAL HEALTH CARE ENFORCEMENT TOOLS

While most health care attorneys are familiar with the government's traditional arsenal of enforcement tools, a brief recitation of these authorities is useful, particularly as these tools have several limitations, explored in greater detail below.

1 Press Release, DOJ, Attorney General Sessions Delivers Remarks Announcing National Health Care Fraud and Opioid Takedown, June 28, 2018, https://www.justice.gov/opa/speech/attorney-general-sessions-delivers-remarks-announcing-national-health-care-fraud-and.

2 For example, in April 2019, DOJ announced federal indictments and arrests for "one of the largest health care fraud schemes" resulting in allegedly $1.2 billion in losses. *See* Press Release, DOJ, Federal Indictments & Law Enforcement Actions in One of the Largest Health Care Fraud Schemes Involving Telemedicine and Durable Medical Equipment Marketing Executives Results in Charges Against 24 Individuals Responsible for Over $1.2 Billion Losses, Apr. 9, 2019, https://www.justice.gov/opa/pr/federal-indictments-and-law-enforcement-actions-one-largest-health-care-fraud-schemes. Then, just five months later, DOJ announced charges against 35 individuals for a scheme involving over $2.1 billion in alleged losses. *See* Press Release, Federal Law Enforcement Action Involving Fraudulent Genetic Testing Results in Charges Against 35 Individuals Responsible for Over $2.1 Billion in Losses in One of the Largest Health Care Fraud Schemes Ever Charged, Sept. 27, 2019, https://www.justice.gov/opa/pr/federal-law-enforcement-action-involving-fraudulent-genetic-testing-results-charges-against.

### False Claims Act

The government's primary tool in tackling health care fraud has historically been the False Claims Act (FCA). The statute was originally enacted in 1863 in response to concerns about military suppliers defrauding the Union Army during the Civil War. While the statute originally was enacted in response to procurement fraud, the FCA is primarily utilized today in response to allegations concerning health care fraud.[3] In broad strokes, the FCA provides that any person who knowingly submits false claims to the government is liable up to treble the government's damages plus monetary penalties.

The statute sets forth liability for any person who knowingly submits a false claim to the government or causes another to submit a false claim to the government or knowingly makes a false record or statement to get a false claim paid by the government.[4] The statute also provides liability where one acts improperly—not to get money from the government, but to avoid having to pay money to the government.[5]

Notably, the False Claims Act only allows the government to tackle alleged fraud involving *federal health care payers* (e.g., Medicare, Medicaid, TRICARE). Where the alleged fraudulent conduct does not affect the federal government, the FCA has no applicability.[6] Further, the FCA has been limited in its applicability in recent years by judicial opinions that have narrowed the statute's reach. For example, in a recent case before the Supreme Court, the Court cut back on the False Claims Act by ruling that the false certification theory of liability required that a claim "does not merely request payment, but also makes specific representations about the goods or services provided; and [] the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths."[7] In so holding, the Supreme Court noted that this test was a "rigorous" and "demanding" standard. Put another way, the government could only prevail if it was demonstrated that the government would have refused to pay if it knew of the alleged misrepresentations.

---

3 *See, e.g.,* Press Release, DOJ, Justice Department Recovers Over $2.8 Billion from False Claims Act Cases in Fiscal Year 2018, Dec. 21, 2018, https://www.justice.gov/opa/pr/justice-department-recovers-over-28-billion-false-claims-act-cases-fiscal-year-2018 (noting that, of the $2.8 billion recovered in 2018 pursuant to the False Claims Act, "$2.5 billion involved the health care industry, including drug and medical device manufacturers, managed care providers, hospitals, pharmacies, hospice organizations, laboratories, and physicians"). To be sure, the FCA is still utilized to pursue procurement fraud claims.

4 *See* 31 U.S.C. § 3729(a)(1)(A)-(B) (2019).

5 *Id.* § 3729(a)(1)(G).

6 Relatedly, where the alleged fraud scheme involves both federal and non-federal payers, under the FCA, the government can only pursue the losses to the federal payers and has no recourse to losses to the non-federal payers.

7 *See* United Health Servs. v. United States *ex rel.* Escobar, 136 S. Ct. 1989, 2001 (2016).

These recent judicial opinions have meaningfully slowed the otherwise steady increased use of the FCA. In one of the more notable examples of the effect of these recent judicial decisions, a district court in Florida vacated a nearly $350 million jury verdict, finding that the plaintiffs had not shown that the alleged fraud was "material."[8] There, the plaintiffs alleged that nursing homes had failed to keep proper documentation showing that services were medically necessary. The district court reversed, finding that the documentation issues were not material to the government's payment decisions.

While FCA civil actions continue to remain in vogue, and while the government continues to recover substantial money through these cases, there are subtle signs that DOJ's use of the statute is waning from its heyday. For example, in 2018—the year for which most recent information is available—the Justice Department collected $2.9 billion through FCA recoveries. While this is no doubt impressive, this is nearly 25% less than collections from the FCA just one year before.[9] Moreover, the Department's FCA recoveries in 2018 are the lowest in at least a decade. Nonetheless, any discussion of DOJ's arsenal of health care enforcement tools almost certainly begins with a discussion of the False Claims Act.

### Health Care Fraud

On the criminal side, the government's primary tool for health care fraud enforcement is the general health care fraud statute, 18 U.S.C. § 1347. By its terms, the statute punishes anyone who "knowingly and willfully executes, or attempts to execute, a scheme or artifice . . . to defraud any health care benefit program."

While perhaps obvious from the text itself, the statute requires the government to prove three elements. First, the government must show that the defendant executed a scheme to defraud any health care benefit program (or attempted to do so). Second, the government must show that the fraud was in connection with the delivery or payment of health care benefits or services. And, third, the government must prove that the defendant acted "knowingly and willfully."

Unlike the civil False Claims Act analogue, the general health care fraud statute applies to any "health care benefit program." While DOJ has historically focused its

8 *See* United States *ex rel.* Ruckh v. CMC II LLC et. al, No. 8:2011-cv-01303, Document 468 (M.D. Fla. 2018).

9 *See* Press Release, DOJ, Justice Department Recovers Over $3.7 Billion From False Claims Act Cases in Fiscal Year 2017, Dec. 21, 2017, https://www.justice.gov/opa/pr/justice-department-recovers-over-37-billion-false-claims-act-cases-fiscal-year-2017.

efforts on federal health care payers, DOJ has also applied the general health care fraud statute to conduct affecting private payers.[10]

### Anti-Kickback Statute

Another arsenal used in the criminal—and increasingly, in the FCA—context, is the Anti-Kickback Statute (AKS), which prohibits the knowing and willful offer, payment, solicitation, or receipt of any remuneration, in cash or in kind, to induce or in return for referring an individual for the furnishing or arranging of any item or service for which payment may be made under a federal health care program.[11] Importantly, the AKS only applies to federal programs.

As most health care attorneys are painfully aware, "remuneration" under the AKS is broadly defined. Remuneration means anything of value and can include gifts, under-market rent, or payments that are above fair market value for the services provided. Criminal penalties for violation are a fine of up to $25,000 and imprisonment for up to five years.

### Stark Law

Broadly defined, the Stark Law[12] prohibits a physician from referring Medicare patients for designated health services to an entity with which the physician (or immediate family member) has a financial relationship, unless an exception applies.[13] Notably, the Stark Law is only civil in nature. Moreover, it only applies to the Medicare and Medicaid programs.[14] It does not expand to private payers, nor does it apply to government programs other than Medicare or Medicaid.

10 *See, e.g.*, Press Release, DOJ, July 10, 2019, Bay City Vascular Surgeon Charged In Connection With $60 Million Health Care Fraud & Laundering More Than $49 Million Government Seeks Forfeiture Of Approximately $39.9 Million Seized From Defendant, https://www.justice.gov/usao-edmi/pr/bay-city-vascular-surgeon-charged-connection-60-million-health-care-fraud-laundering (charging a defendant with health care fraud for submitting false claims to Blue Cross Blue Shield of Michigan).

11 42 U.S.C. § 1320a-7b(b) (2019). While the AKS is a criminal statute and contains no private right of action, the government and *qui tam* plaintiffs have successfully argued that violations of the AKS, a criminal statute, can serve as the basis for a claim under the False Claims Act. Under this theory, a claim to the government is rendered "false" for purposes of the FCA if the medical services or items were furnished in violation of the AKS notwithstanding the fact that the services or items provided were themselves appropriate and proper.

12 *Id.* § 1395nn.

13 While the text of the Stark Law discusses potential civil monetary penalties imposed by the Department of Health and Human Services, the practical application of this law is through the False Claims Act. By applying the Stark Law through the lenses of the False Claims Act, regulators are able to potentially recover up to treble damages.

14 The Stark Law applies to the Medicaid program through 42 U.S.C. § 1396 (2019).

While the Stark Law, unlike the other statutes listed above, does not contain a meaningful intent standard (indeed, it is a strict liability statute), its reach is limited. Apart from the limitation that it only applies to Medicare and Medicaid, the statute only applies to "designated health services," some of which are defined by a specified list of procedure codes.[15] It is also limited only to those situations in which a physician or an immediate family member has a financial relationship with the entity to which the physician refers the patient for the designated health care service.

Broadly defined, these statutes have been the traditional quivers in the government's arsenal. However, as explained immediately below, these tools are increasingly being used in conjunction with more novel statutes and authorities.

## NON-TRADITIONAL HEALTH CARE ENFORCEMENT TOOLS

In the past two years, DOJ has increasingly dug deeper in its arsenal to prosecute alleged wrongdoers. Several of these new tools are described in detail below.

### Travel Act

The Travel Act broadly prohibits the interstate travel or transportation in certain "unlawful activity."[16] The Act was initially enacted in 1961 to address organized crime and the scourge of gambling, liquor, and prostitution. While the Act made clear that interstate gambling, liquor, and/or prostitution were explicitly prohibited unlawful acts, the statute also noted that those who traveled across interstate lines to engage in violations of state bribery laws could also be punished.[17] The key *federal* nexus to the Travel Act was that an individual had to be crossing state lines to participate in these unlawful acts.

---

15 The category of designated health services is defined in regulation at 42 C.F.R. § 411.351 (2020). The Center for Medicare and Medicaid Services provides a list on its website. *See Code List for Certain Designated Health Services (DHS)*, CMS, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes.html (last updated Dec. 2, 2019).

16 18 U.S.C. § 1952.

17 *See id*. § 1952(b) ("As used in this section (i) 'unlawful activity' means (1) any business enterprise involving gambling, liquor on which the Federal excise tax has not been paid, narcotics or controlled substances (as defined in section 102(6) of the Controlled Substances Act), or prostitution offenses in violation of the laws of the State in which they are committed or of the United States, (2) extortion, bribery, or arson in violation of the laws of the State in which they are committed or of the United States, or (3) any act which is indictable under subchapter II of chapter 53 of title 31, United States Code, or under section 1956 or 1957 of this title and (ii) the term "State" includes a State of the United States, the District of Columbia, and any commonwealth, territory, or possession of the United States.").

To make out a viable case involving the Travel Act, the government must show some interstate nexus (e.g., travel, mailings, etc.), the intent to engage in some unlawful activity, and some overt act in furtherance of the scheme. Given these basic elements, some prosecutors in recent years have used the Travel Act in original ways—specifically, to criminalize kickbacks in the private insurance market.[18] In a high-profile prosecution in April 2019, federal prosecutors relied on Texas' commercial bribery laws to convict nearly a dozen physicians and executives for conduct that would not otherwise be actionable under federal health care statutes, but for the Travel Act.[19] Under this theory, the payment of remuneration—traditionally considered a "kickback"—could be actionable even in the private insurance space provided that the government could show that the payment constitutes a violation of state bribery laws.

The government's tackling of kickbacks in the private insurance space is increasingly drawing attention from onlookers—and the recent high-profile prosecution in Texas of physicians and executives is not the only example of prosecutors' use of the Travel Act in recent years. For example, a year earlier and a thousand miles away, federal prosecutors used the Travel Act to convict executives associated with Biodiagnostic Laboratory Services, LLC.[20] Similar to the Texas case, prosecutors here relied on state bribery laws—specifically laws from New Jersey—to hold health care professionals liable under federal law.

The use of the Travel Act is worrisome for health care practitioners for several reasons. First, until recently, it had been a bedrock principle that the Anti-Kickback Statute prohibitions applied only to federal payers such as Medicare and Medicaid. Those principles have less support now given the expansive use of the Travel Act. Second, the Travel Act, unlike the health care fraud statute, does not require any finding of "fraud." This is not an academic distinction. For cases rooted in fraud, such as health care fraud, the government normally is subject to a strict pleading standard and is required to generally prove the alleged fraud with particularity—such as providing information about the quintessential who, what, where, when, and why. In non-fraud cases, such as bribery cases, the government is not subject to these same strictures. Instead, the government's standard is to simply prove payments intended to

18 *See* Press Release, DOJ, Seven Guilty in Forest Park Healthcare Fraud Trial, Apr. 10, 2019, https://www.justice.gov/usao-ndtx/pr/seven-guilty-forest-park-healthcare-fraud-trial (explaining that the defendants were charged with both kickback charges and Travel Act violations).

19 *Id.*

20 *See* Press Release, DOJ, Five Former Salesmen For Morris County Clinical Lab Sentenced For Bribing Doctors In $100 Million Test Referral Scheme, May 17, 2018, https://www.justice.gov/usao-nj/pr/five-former-salesmen-morris-county-clinical-lab-sentenced-bribing-doctors-100-million.

induce improper actions. This lesser standard removes the particularity requirements. Thus, the more rigorous dictates usually required of fraud cases have fallen by the wayside in these more aggressive prosecutions.

Given prosecutors' increasing use of this statute, practitioners would be well-advised to treat all potential problematic financial arrangements—not just those involving federal health care programs—as potentially prosecutable.

### Racketeering Influenced and Corrupt Organizations Act

Another emerging tool in health care prosecutors' arsenal is the selective use of the Racketeering Influenced and Corrupt Organizations (RICO) Act. When passed in 1970, the RICO statute was intended to facilitate "the elimination of the infiltration of organized crime and racketeering into legitimate organizations operating in interstate commerce."[21] However, the statute is sufficiently broad to encompass illegal activities relating to almost any enterprise affecting interstate or foreign commerce.

Like the Travel Act, the RICO Act's reach stems in part from its ability to allow federal prosecutors to use state law violations to make out a federal crime.[22] Broadly defined, to make out an actionable RICO case, prosecutors must show four elements: "(1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity."[23] While an exhaustive description of these elements could take literally hundreds of pages,[24] a few salient points are worthy of explicit mention.

First, under the RICO statute, "racketeering activity" includes state offenses for a number of crimes—many of which have very little connection to health care—and also includes more than one hundred serious federal offenses, including extortion, interstate theft, narcotics violations, mail fraud, securities fraud, currency reporting violations, certain immigration offenses, and terrorism-related offenses. Second, to show a "pattern" of activity, prosecutors merely need to show any combination of two or more of these state or federal crimes committed within a statutorily prescribed time period (typically over a year). These two guiding posts—the inclusion of hundreds of possible

21 S. Rep. No. 617, 91st Cong., 1st Sess. 76 (1969).

22 *See, e.g.*, Justice Manual § 9-110.200, https://www.justice.gov/jm/jm-9-110000-organized-crime-and-racketeering#9-110.210 (last updated Jan. 2019) ("Utilization of the RICO statute, more so than most other federal criminal sanctions, requires particularly careful and reasoned application, because, among other things, RICO incorporates certain state crimes.").

23 Sedima v. Imrex Co., 473 U.S. 479, 496 (1985).

24 In fact, the Department of Justice has a 556-page guide devoted solely to the particulars of the RICO Act. *See* Criminal RICO: 18 U.S.C. §§ 1961-1968: A Manual For Federal Prosecutors (6th ed. 2016), https://www.justice.gov/usam/file/870856/download.

acts and the small number of acts required—can often lead to significant prosecutions for conduct that practitioners might not have appreciated as rising to a federal level.

The most high-profile example of DOJ's use of the RICO Act in the health care context was the recent prosecution of Insys Therapeutics, a company that created a fentanyl spray intended for cancer patients.[25] In that case, prosecutors alleged that seven executives conspired to mislead and defraud health insurance providers who were reluctant to approve payment for the drug when it was prescribed for non-cancer patients. Prosecutors alleged that Insys achieved this goal of misleading insurers by setting up the "reimbursement unit," which was dedicated to obtaining prior authorization directly from insurers and pharmacy benefit managers.[26]

In the Insys case, prosecutors successfully relied on the RICO Act's use of various state statutes to cobble together a comprehensive case against the defendants. Among other "predicate" offenses to establish racketeering, prosecutors relied on violations of drug distribution laws, mail and wire fraud, and breach of the duty of honest services.[27] As demonstrated by the Insys case, the benefit of relying on the RICO Act is that prosecutors are able to group a series of defendants in a purported "racketeering" enterprise and then introduce a variety of disparate evidence to establish the violations of federal law.

Importantly, one of the collateral effects of the use of the RICO Act is that prosecutors, after obtaining a conviction, can avail themselves of the Act's mandatory asset forfeiture provisions.[28] Under RICO's mandatory asset forfeiture provisions, "[a]ny person convicted of a violation . . . shall forfeit to the United States . . . (1) any property constituting, or derived from, any proceeds the person obtained, directly or indirectly, as the result of such violation." (emphasis added). Therefore, at sentencing, while judges might have discretion in typical health care fraud cases to tailor a restitution and forfeiture order that is consistent with the defendant's actual ill-gotten gains (or reflective of the defendant's personal circumstances), this discretion is significantly curtailed under RICO. This is a significant tool for the government to deter health care practitioners from activities that the government views as fraudulent.

25 *See* Press Release, DOJ, Founder and Owner of Pharmaceutical Company Insys Arrested and Charged with Racketeering, Oct. 26, 2017, https://www.justice.gov/opa/pr/founder-and-owner-pharmaceutical-company-insys-arrested-and-charged-racketeering.

26 *Id.*

27 *See* Peter J. Henning, *RICO Offers a Powerful Tool to Punish Executives for the Opioid Crisis*, N.Y. Times, May 23, 2019, https://www.nytimes.com/2019/05/23/business/dealbook/rico-insys-opioid-executives.html.

28 21 U.S.C. § 853(a) (2019).

In large part because of prosecutors' success using RICO in the Insys matter, some commentators have suggested that "it would hardly be surprising if RICO became the tool of choice for federal prosecutors looking to build a case against pharmaceutical executives."[29]

### Eliminating Kickbacks in Recovery Act

Finally, an emerging tool of choice for prosecutors is the newly enacted Eliminating Kickbacks in Recovery Act (EKRA). Passed in 2018, EKRA reflects Congress's bipartisan concern with the proliferation of patient brokers who profited in the substance abuse space.

Broadly defined, EKRA prohibits knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in return for the referral of a patient to, or in exchange for an individual using the services of, a recovery home, clinical treatment facility, or laboratory if the services are covered by a health care benefit program. Importantly, the term "health care benefit program" includes "any public or private plan or contract, affecting commerce, under which any medical benefit, item, or service is provided to any individual, and includes any individual or entity who is providing a medical benefit, item, or service for which payment may be made under the plan or contract."[30] Therefore, unlike the Anti-Kickback Statute referenced earlier, EKRA's reach explicitly extends to referrals reimbursed by both government and private insurers.[31]

Importantly, while EKRA was passed in concert with a substance abuse act law, the literal text of EKRA extends to all laboratory testing, regardless of whether the laboratory tests are related to substance abuse.

Given the recent passage of EKRA, there does not appear to be any prosecution that directly reflect this new weapon in DOJ's arsenal, but several past cases of related conduct provide likely clues as to how EKRA will bolster DOJ's prosecution tactics. For

29 Peter J. Henning, *RICO Offers a Powerful Tool to Punish Executives for the Opioid Crisis*, N.Y. Times, May 23, 2019, https://www.nytimes.com/2019/05/23/business/dealbook/rico-insys-opioid-executives.html.

30 18 U.S.C. § 24(b). An important open question is whether defendants might try to argue that EKRA's reach is limited in that it purports to govern only health care programs that affect federal commerce, as opposed to purely intrastate commerce. Imagine a local drug rehabilitation center that only caters to a very geographically limited patient population. It is unclear whether EKRA might govern that center and tests emanating from that center. However, given the courts' broad interpretation of the interstate commerce definition, this argument might be purely academic, rather than a practical limitation.

31 EKRA does explicitly identify certain conduct and arrangements that do not run afoul of the criminal statute. Nonetheless, unless an arrangement specifically falls within one of these exceptions, the statute's broad reach means that a host of referral conduct may not be prosecuted, regardless of payer.

example, in late 2016, prosecutors in Southern Florida charged six individuals with patient brokering and improper kickbacks relating to the drug addiction treatment space.[32] The government successfully contended that these individuals engaged in health care fraud to obtain medically unnecessary urine toxicology tests. These tests were not paid by federal payers, so the Anti-Kickback Statute was not applicable. Therefore, to obtain these convictions, prosecutors needed to be able to prove that this conduct amounted to "health care fraud" and, further, that the tests were medically unnecessary.

In the post-EKRA world, it is unclear that prosecutors would have needed to prove as many facts to obtain the same conviction. Instead of having to prove that the tests were unnecessary, for example, prosecutors would simply need to prove that the defendants received remuneration in exchange for the referral of these toxicology tests. A case that consumed considerable resources and involved significant litigation risk would likely be significantly streamlined in light of EKRA.

It is further noteworthy that, while the statute is still relatively new and few cases have directly cited to this statute, DOJ appears to be using the strictures of EKRA in building some of its recent cases against those involved in the cancer testing and genetic testing space. For example, in the recent indictment against Lab Solutions' owner Minal Patel,[33] the government focused solely on the remuneration arrangements for the provision of certain laboratory tests, rather than focusing on the medical necessity of these tests or the otherwise alleged fraudulent conduct giving rise to the ordering of these tests. This focus on the remuneration inherent in the provision of these tests is consistent with EKRA's broader prohibitions on patient brokering and split fees.

## PRACTICAL CONSIDERATIONS

Clearly, the stakes have ramped up for health care practitioners in light of DOJ's increasing use of new statutes. Conduct that once seemed beyond the reach is now seemingly in play by DOJ's use of statutes such as the Travel Act, RICO, and EKRA. These new statutes—and the government's willingness to use these statutes—means that practitioners and those advising them will need to revisit their compliance strategies. Offered below are a few suggestions for dealing with these new quivers.

32 *See* Press Release, DOJ, Six Defendants Charged in Health Care Fraud Scheme Involving Sober Homes and Alcohol and Drug Addiction Treatment Centers, Dec. 21, 2016, https://www.justice.gov/usao-sdfl/pr/six-defendants-charged-health-care-fraud-scheme-involving-sober-homes-and-alcohol-and.

33 *See* United States v. Patel, 9:19-cr-80181 (S.D. Fl. Sept. 24, 2019).

- Now is a good time to carefully review all arrangements, contracts, and relationships that involve financial payments (including collection and/or waiver of co-pays) related to health care services. What was once defensible as carving out federal health care program business may no longer be defensible today. Therefore, a global review of all financial arrangements is well-advised. The government is clearly focused on the role that financial incentives play in affecting health care services. Accordingly, any time that monetary inducements could affect the ordering or referring of health care services, practitioners should tread carefully.
- Practitioners now, more than ever, need to stay abreast of prosecutors' increasingly novel applications of state laws to federal prosecutions. For example, as prosecutors continue to apply state laws regarding bribery to federal cases, practitioners would be well-served to check their clients' contracts and arrangements to make sure they comport with not just federal law but also various, oftentimes tangential, state laws.
- Given the broad statutory language of EKRA, practitioners should appreciate that the government has cast a negative light on commission-based payments. While commissions are commonplace in many industries, they are very much a disfavored payment mechanism in the health care setting (precisely because commissions often incentivize over-utilization). Given this broad brush, practitioners should steer away from incentive-based payments as much as possible.
- While some of these novel prosecutions have somewhat weakened the government's burden of proof, an actionable prosecution still may only be brought when the government can show an improper intent. Therefore, practitioners are advised to contemporaneously document their intentions and purposes *before* entering into new financial arrangements or transactions. This contemporaneous documentation is powerful evidence to negate prosecutors' theories of improper intent.
- Finally, both the federal government and many state regulatory bodies have processes whereby practitioners can petition for declaratory statements and other prospective guidance prior to entering into financial transactions. Practitioners may wish to consider taking this approach in certain contexts in light of these new prosecutions.

## CONCLUSION

Most health care clients understand the perilous regulatory climate, and the significant consequences for even inadvertent mistakes. Unfortunately, the new prosecutorial environment has become even more stark and ominous in light of these recent developments. Treading carefully while the government continues to develop its prosecution strategies is strongly advised. In addition, prospectively seeking guidance from regulators is more advisable than ever. Indeed, as the adage goes, an ounce of prevention is worth a pound of cure. J

# Author Profiles

**A. LEE BENTLEY III** is a Partner in Bradley's Government Enforcement and Investigations Practice Group, where he defends False Claims Act and qui tam cases, internal investigations, and white-collar criminal matters. His practice is focused on telemedicine/telehealth, compound pharmacy, and urine toxicology cases, among other alleged fraud schemes. His experience also includes complex civil litigation involving government entities, and he has handled trials and appeals in numerous federal and state courts. Prior to joining Bradley, Lee was the United States Attorney for the U.S. Attorney's Office for the Middle District of Florida, where he oversaw more than 120 civil and criminal prosecutors. He was previously in private practice in both Washington, D.C., and Atlanta, and served as a Special Assistant United States Attorney and an attorney advisor for the U.S. Department of Justice, Office of Legal Counsel. Contact him via email at lbentley@bradley.com.

**JASON P. MEHTA** is a Partner in Bradley's Government Enforcement and Investigations Practice Group, where he advises clients on bet-the-company litigation and investigations. His practice involves responding to and defending government investigations, asset forfeiture actions, False Claims Act and qui tam cases, and business litigation matters. Jason handles sensitive and high-profile criminal and civil matters in courts across the country, defending executives in health care criminal matters, corporations in complex qui tam investigations, and companies in litigation in significant, multibillion-dollar cases. He routinely counsels private health care, banking and other clients on compliance and proactive defense strategies. Prior to joining Bradley, Jason served as an Assistant United States Attorney for the U.S. Attorney's Office in Jacksonville, Florida, and worked as an attorney-adviser for the U.S. Department of State in Washington, D.C., where he led the department's responses to various Congressional investigations and represented the department in lawsuits throughout the country. Contact him via email at jmehta@bradley.com.


**American Health Lawyers Association**
1620 Eye Street, NW, 6th Floor • Washington, DC 20006-4010
(202) 833-1100 • Fax (202) 833-1105 • www.healthlawyers.org