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The Devil Made Me Do It: An Argument for Expanding the Anti-Kickback Statute to Cover Private Payers

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The Devil Made Me Do It: An Argument for Expanding the Anti-Kickback Statute to Cover Private Payers

CHINELO DIKÉ-MINOR

Private health insurance is the predominant source of health insurance coverage in the United States. Yet, the primary criminal anti-kickback law in the United States, the Anti-Kickback Statute, applies only to certain government-funded health insurance payers. This Article argues that the Anti-Kickback Statute should be expanded to protect all health insurance payers, including private ones. First, the harms that kickbacks cause—overutilization and fraud, patient harm, and an undermining of a competitive health care market—extend to private payers and their beneficiaries and any harms unique to government payers can be addressed through sentencing enhancements. Second, Congress has previously justified excluding private payers from the protections of the Anti-Kickback Statute on the grounds that as managed care entities, they are immune to kickback harms. That rationale, however, does not fare well against the facts: many private payers use fee-for-service models, many government payers use managed care models, and kickbacks can cause harm even under a managed care model. Further, concerns with the Anti-Kickback Statute’s interaction with managed care can be addressed through safe harbors. Third, excluding private payers from the Anti-Kickback Statute’s protections hampers prosecutors’ ability to address health care fraud because it results in fraud shifting, creates unnecessary intent problems, and forces prosecutors to charge cases in ways that do not fully reflect defendants’ conduct. Furthermore, the problems that accompany the Anti-Kickback Statute’s narrow reach are not resolved by looking to other federal laws. Existing laws such as the Eliminating Kickbacks in Recovery Act, the Criminal Health Care Fraud Statute, the Travel Act, and the Honest Services

Fraud Statute do not adequately fill the gap. Similarly, state laws and private claims by private payers are also inadequate gap-fillers, particularly given that not all states have anti-kickback laws. Moreover, the multi-state nature of health care fraud, the resources required to address this conduct, and skyrocketing health care costs, caused partly by health care fraud, warrant federal engagement.

ARTICLE CONTENTS

INTRODUCTION	91
I. KICKBACKS AND THE HARMS THEY CAUSE.....	93
A. KICKBACKS CAUSE OVERUTILIZATION.....	95
B. KICKBACKS CAUSE PATIENT HARM.....	97
C. KICKBACKS IMPEDE A COMPETITIVE MARKET	99
II. KICKBACK AND PAYMENT-FOCUSED LAWS	99
A. CIVIL LAWS.....	99
B. CRIMINAL LAWS	101
III. CONGRESS SHOULD EXPAND THE ANTI-KICKBACK STATUTE TO PROTECT PRIVATE PAYERS	105
A. KICKBACK HARMS ALSO AFFECT PRIVATE PAYERS.....	105
B. THE “PRIVATE PLANS ARE MANAGED CARE PLANS” RATIONALE FALLS SHORT	111
C. EXCLUDING PRIVATE PAYERS HAMPERS PROSECUTORS’ ABILITY TO ADDRESS HEALTH CARE FRAUD.....	118
IV. EXISTING LAWS DO NOT ADEQUATELY ADDRESS THE PROBLEM	120
A. ELIMINATING KICKBACKS IN RECOVERY ACT	121
B. THE CRIMINAL HEALTH CARE FRAUD STATUTE.....	122
C. TRAVEL ACT	124
D. THE HONEST SERVICES FRAUD STATUTE	126
V. A FEDERAL SOLUTION IS NEEDED	129
A. “LEAVE IT TO THE STATES” IS NOT A SOLUTION.....	129
B. PRIVATE PAYERS CANNOT ADDRESS THE PROBLEM ON THEIR OWN	131
CONCLUSION.....	132



The Devil Made Me Do It: An Argument for Expanding the Anti-Kickback Statute to Cover Private Payers

CHINELO DIKÉ-MINOR*

INTRODUCTION

Somewhere in America . . .

Sales Representative A, a sales representative for a compounded cream pharmacy, pays Doctor A \$50 for each compounded cream for pain and scars that Doctor A prescribes for patients with government-funded health insurance (e.g., Medicare and Medicaid), that is filled—and therefore billed—by Sales Representative A’s pharmacy.

Sales Representative B, also a sales representative for a compounded cream pharmacy, pays Doctor B \$50 for each compounded cream, also for pain and scars, that Doctor B prescribes but only for patients with private health insurance. Indeed, Doctor B only sees patients with private health insurance. As with Sales Representative A, the creams would be filled and billed by Sales Representative B’s pharmacy.

Notwithstanding this almost identical conduct, only Sales Representative A and Doctor A could be prosecuted under the United States’ criminal anti-kickback laws. This is because, with one small exception for

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opioid-related conduct, those laws protect only government-funded health insurance payers like Medicare, Medicaid, and TRICARE.¹ This is so, even though “private health insurance is the predominant source of health insurance coverage in the United States,”² accounting for almost thirty percent of health insurance spending³ with approximately seventy percent of Americans covered by private health insurance.⁴

This Article argues that anti-kickback laws, specifically, the Anti-Kickback Statute, should be expanded to protect all health insurance payers, including private ones for several reasons. First, the harms that kickbacks cause—overutilization and fraud, patient harm, and an undermining of a competitive health care market—extend to private payers and their beneficiaries. In addition, any harms unique to government payers and their beneficiaries can be addressed through sentencing enhancements.⁵ Second, although Congress has previously justified excluding private payers from the protections of the Anti-Kickback Statute on the grounds that as managed care entities, they are immune to kickback harms,⁶ that rationale does not fare well against the facts. Many private payers use fee-for-service models, many government payers use managed care models, and kickbacks can cause harm even under a managed care model. In addition, concerns with the Anti-Kickback Statute’s interaction with managed care can be—and already are to some degree—addressed through safe harbors. Third, excluding private payers from the Anti-Kickback Statute’s protections hampers prosecutors’ ability to address health care fraud because it results in fraud shifting, creates unnecessary intent problems, and forces prosecutors to charge cases in ways that do not fully reflect defendants’ conduct.

Furthermore, the problems that accompany the Anti-Kickback Statute’s narrow reach are not resolved by looking to other federal laws. Existing laws such as the Eliminating Kickbacks in Recovery Act, the Criminal Health Care Fraud Statute, the Travel Act, and the Honest Services Fraud Statute do not adequately fill the gap. Similarly, state laws and private actions by

¹ 42 U.S.C. § 1320a-7b(b). A brief note on language. The term “payer” (or “payor”) refers to “any organization that administers health benefits and pays providers.” PETER R. KONGSTVEDT, *ESSENTIALS OF MANAGED HEALTH CARE* 22 (6th ed. 2013). Although their meanings are narrower (e.g., “health plan” more precisely refers to the entity “responsible for setting the benefits and bearing the risk for medical costs”), “health plan” and “health insurer” or “insurer” are often used interchangeably with “payer,” and this article will do the same. *Id.* at 22–23.

² RYAN J. ROSSO, CONG. RSCH. SERV., IF10830, *U.S. HEALTH CARE COVERAGE & SPENDING* (2023).

³ *Id.* (“Private health insurance expenditures include amounts paid by insuring organizations to providers and all insuring organizations’ nonmedical net costs, which include but are not limited to taxes, net gains or losses to reserves, and profits.”).

⁴ *Id.* This data is from 2021 and the specific percentage is 68.4%, with 54.7% getting their care through private group health insurance (e.g., employer-sponsored insurance), and 13.7% through the non-group market (e.g., via the Affordable Care Act market exchanges).

⁵ This Article will use the terms “patients” and “beneficiaries” interchangeably.

⁶ Chinelo Diké-Minor, *The Untold Story of the United States’ Anti-Kickback Laws*, 20 *RUTGERS J.L. & PUB. POL’Y* 103, 146 (2023).

private payers are insufficient tools to address kickback conduct because not all states have anti-kickback laws. Moreover, the multi-state nature of health care fraud, the resources required to address it, and skyrocketing health care costs, caused partly by health care fraud, warrant federal engagement.

This Article proceeds as follows. Part I discusses the rationale for prohibiting kickbacks in the health care space by describing the harms that kickbacks cause: overutilization, patient harm, and harm to a competitive market. Part II provides an overview of the various payment-focused laws Congress has passed to address these harms, by briefly outlining both the existing civil and criminal kickback laws. It then gives a more detailed overview of the two criminal anti-kickback laws, the Anti-Kickback Statute and Eliminating Kickbacks in Recovery Act (EKRA) to set the stage for explaining why the Anti-Kickback Statute should be expanded. Part III argues that the Anti-Kickback Statute should be expanded to private payers, for the three reasons described above. Part IV explains why the already existing relevant federal laws, including the only other criminal kickback statute, EKRA, do not address the problem. Finally, Part V explains why a federal solution is needed and why it is insufficient to defer to the states or private plans to address this problem.

I. KICKBACKS AND THE HARMS THEY CAUSE

A kickback is a referral fee.⁷ It is a payment or reward for a referral, either with money (e.g., cash, checks) or goods or services (e.g., rent-free use of a facility).⁸ Although referral fees are both commonplace and permitted in many industries, they are frowned upon in the health care context, and indeed are assigned the much more insidious sounding “kickback” label.⁹ Why? Because certain distinctive characteristics of the health care industry transform kickbacks into a poison that can cause significant harm to the health care system, patients, and market.¹⁰

These distinctive characteristics are two-fold. The first characteristic is the prevalence of referrals in health care. The second is patients’ almost complete reliance on providers for medical advice and guidance. Richard P. Kusserow, a former Inspector General of the United States Department of Health and Human Services, explained:

In the health care industry, referrals are a potent source of business. Because consumers are less knowledgeable about medical issues, they rely on medical experts for referrals.

⁷ *Fraud & Abuse Laws*, U.S. DEP’T OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., <https://oig.hhs.gov/compliance/physician-education/fraud-abuse-laws/> (last visited Aug. 3, 2023) [hereinafter *HHS-OIG Fraud & Abuse Laws*].

⁸ *Id.*

⁹ *Id.*

¹⁰ Richard P. Kusserow, *The Medicare & Medicaid Anti-Kickback Statute and the Safe Harbor Regulations—What’s Next?*, 2 HEALTH MATRIX 49, 52 (1992).

Thus, there is a tremendous temptation to offer economic incentives to those who can influence the flow of business.¹¹

When combined with kickbacks, these two unique characteristics—referrals and reliance—encourage bad behavior, primarily the referral of medically unnecessary, lower quality, and more expensive products and services.¹² The likelihood of this bad behavior is perhaps so obvious that at least one court has described kickbacks in the health care context as “*malum in se*,”¹³ i.e., “[s]omething intrinsically evil or wicked,”¹⁴ or devilish, as the title of this Article suggests.¹⁵

To illustrate how referrals and reliance combine with kickbacks to poison a doctor’s judgment, recall our hypothetical Doctors *A* and *B*. The fifty dollars per prescription kickback would incentivize both to prescribe Sales Representatives *A* and *B*’s compounded creams. To increase their earnings, Doctors *A* and *B* might prescribe the creams for more patients than they otherwise would have, even if their patients did not need them, and even if the creams were of lower quality and more expensive than others available. Doctors *A* and *B* will expect to get away with it because writing prescriptions (a form of referrals¹⁶) is a routine and expected part of their job that requires an understanding of the specific patient’s health history and

¹¹ *Id.* See also Joan H. Krause, *A Patient-Centered Approach to Health Care Fraud Recovery*, 96 J. CRIM. L. & CRIMINOLOGY 579, 582–83, 587–95 (2006) [hereinafter Krause, *A Patient-Centered Approach*] (discussing the ways that health care fraud harms patients).

¹² See U.S. GOV’T ACCOUNTABILITY OFF., GAO/HRD-92-69, HEALTH INSURANCE: VULNERABLE PAYERS LOSE BILLIONS TO FRAUD AND ABUSE 9 (1992) (“Because kickbacks constitute payments to induce services, they increase insurers’ vulnerability to claims for unnecessary services.”); *United States v. Greber*, 760 F.2d 68, 71 (3d Cir. 1985) (“Testimony before the Congressional committee was that ‘physicians often determine which laboratories would do the test work for their medicaid patients by the amount of the kickbacks and rebates offered by the laboratory. . . . Kickbacks take a number of forms including cash, long-term credit arrangements, gifts, supplies and equipment, and the furnishing of business machines.’”). *Id.* (noting that in amending the Anti-Kickback Statute in 1977, “a particular concern [for Congress] was the practice of giving ‘kickbacks’ to encourage the referral of work.”); *Hanlester Network v. Shalala*, 51 F.3d 1390, 1396 (9th Cir. 1995) (noting that Congress was “concerned with escalating fraud and abuse in the Medicare-Medicaid system.”); *United States v. Patel*, 778 F.3d 607, 617 (7th Cir. 2015) (“[T]he prospect of a kickback gave [the defendant] an increased incentive to charge Medicare for these services—exactly the type of incentive that Congress sought to eliminate by passing the Anti-Kickback Statute.”); *United States v. Ruttenberg*, 625 F.2d 173, 177 n.9 (7th Cir. 1980) (“[K]ickback schemes . . . can erect strong temptations to order more drugs and supplies than needed.”).

¹³ *United States v. Starks*, 157 F.3d 833, 838 (11th Cir. 1998) (“[T]he giving or taking of kickbacks for medical referrals is hardly the sort of activity a person might expect to be legal; . . . such kickbacks are more clearly *malum in se*, rather than *malum prohibitum*.”).

¹⁴ *Malum in se*, OXFORD ENGLISH DICTIONARY, <https://www.oed.com/search/dictionary/?scope=Entries&q=malum+in+se> (last visited Oct. 9, 2023). In contrast, *malum prohibitum* means “[s]omething which is not intrinsically wicked, but which is regarded as wrong because it contravenes a law or regulation.” *Malum prohibitum*, OXFORD ENGLISH DICTIONARY, <https://www.oed.com/search/dictionary/?scope=Entries&q=malum+prohibitum> (last visited Oct. 9, 2023).

¹⁵ The quote in the title of this Article comes from a Senate hearing on Medicare fraud and abuse. *Medicare Fraud and Abuse: Hearing Before the S. Comm. on Finance*, 104th Cong. 17 (1995) (statement of Sen. Cohen) (quoting a physician convicted of health care fraud who testified as an expert witness before the Senate). The full quote refers to fraud more broadly and is: “I just simply could not resist it. It was so easy that I could not resist, the devil made me do it.” *Id.*

¹⁶ Referrals include the writing of prescriptions (e.g., for drugs or durable medical equipment), referrals to a specialist, referrals for a diagnostic test, etc.

needs.¹⁷ Further, Doctors *A* and *B* know that most of their patients trust and rely on their advice and are therefore unlikely to question it.¹⁸ The presence of referrals and reliance therefore creates the temptation to give and accept rewards to providers to make referrals even when those referrals are not in patients' best interests.¹⁹

The following sections explain three harms that result from kickbacks in health care: overutilization, patient harm, and impeding the competitiveness of the health care market.

A. Kickbacks Cause Overutilization

Referring medically unnecessary items and services causes patients to overutilize services, including more expensive but not necessarily higher quality ones.²⁰ This overutilization results in unnecessary health care spending.

A few examples from prosecutions should help illustrate the point. In one case, owners and employees of a compounding pharmacy, Global Compounding Pharmacy (Global), caused the submission of over \$200 million in fraudulent claims to various insurance companies for unnecessary compounded creams.²¹ To make the scheme work, they paid doctors kickbacks, including by hiring their spouses as sales representatives and paying the spouses commissions on each prescription the doctor sent to Global. Unsurprisingly, so incentivized, the doctors began writing millions of dollars' worth of medically unnecessary prescriptions for compounded creams, which were filled by Global.²²

¹⁷ Kusserow, *supra* note 10, at 52.

¹⁸ *Id.*; United States v. Howard, 28 F.4th 180, 207 (11th Cir. 2022) (“A physician who is paid under the table by a pharmacy for writing prescriptions that it fills has an incentive to write more prescriptions, or more costly [or less quality] ones, than she would if acting only in the best medical interests of her patients.”).

¹⁹ *Howard*, 28 F.4th at 207.

²⁰ *Id.* Studies have also shown that physician interactions with industry are linked to a greater willingness to prescribe newer, more expensive drugs. See, e.g., Mary-Margaret Chren & C. Seth Landefeld, *Physicians' Behavior and Their Interactions with Drug Companies: A Controlled Study of Physicians Who Requested Additions to a Hospital Formulary*, 271 JAMA 684, 684 (1994); Chris Watkins, Laurence Moore, Ian Harvey, Patricia Carthy, Elizabeth Robinson, and Richard Brawn, *Characteristics of General Practitioners Who Frequently See Drug Industry Representatives: National Cross Sectional Study*, 326 BRIT. MED. J. 1178, 1178 (2003); Ashley Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?*, 283 JAMA 373, 378 (2000).

²¹ Press Release, U.S. Att’y’s Off., N.D. Ala., Ten, Including Pharmacy Owners, Pharmacist, and Nurse Practitioner, Charged in Over \$200 Million Prescription Drug Fraud (May 6, 2019); Indictment at ¶¶ 34, 94–104, United States v. Adams, No. 6:19-cr-00219 (N.D. Ala. Apr. 24, 2019). The defendants were all convicted. See Press Release, U.S. Att’y’s Off., N.D. Ala., Multiple Defendants Sentenced in a Major Compounding Pharmacy Fraud Conspiracy (Apr. 29, 2021) (The author was a prosecutor on this case.).

²² Indictment at ¶¶ 97, 99, United States v. Adams, No. 6:19-cr-00219 (N.D. Ala. Apr. 24, 2019). See also James M. DuBois, John T. Chibnall, Emily E. Anderson, Heidi A. Walsh, Michelle Eggers, Kari Baldwin, and Kelly K. Dineen, *Exploring Unnecessary Invasive Procedures in the United States: A Retrospective Mixed-Methods Analysis of Cases from 2008-2016*, 11 BIOMED CENT. 1, 7 tbls.4 & 5

In another case, Mohammad Khan, an assistant administrator of Houston's Riverside General Hospital, caused the submission of \$116 million in fraudulent claims to Medicare for a partial hospitalization program, an intensive outpatient treatment for severe mental illness to patients who did not need the services or for whom the services were never provided.²³ To make the scheme work, he paid kickbacks to patient recruiters and owners of assisted living facilities and group care homes to send Medicare beneficiaries to Riverside.²⁴

Now imagine these cases multiple times over.²⁵ Indeed, they are just a drop in the bucket of health care fraud, which is estimated to account for between three and ten percent of health care spending.²⁶ With health care spending reaching \$4.3 trillion in 2021,²⁷ the three and ten percent estimates translate to \$129 billion and \$430 billion respectively—in that one year alone.²⁸ These amounts represent not just the economies of entire states, but

(2017) (A study looking at patient safety in surgery found that in the seventy-nine cases of unnecessary procedures reviewed, the surgeons were almost always (92.4% of the cases) motivated by financial gain, i.e., the possibility of “generat[ing] significant revenue well beyond standard medical practice,” and often (13.9% of the cases) motivated by financial conflicts of interest, i.e., the physician’s “relationship to industry . . . contribute[d] to unnecessary procedures.”).

²³ Press Release, U.S. Dep’t of Just., Off. of Pub. Affs., Assistant Administrator of Houston Hospital Pleads Guilty to Participating in \$116 Million Medicare Fraud Scheme (Feb. 22, 2012).

²⁴ *Id.* To get patients’ buy-in, he also paid them kickbacks “in the form of cigarettes, food and coupons redeemable for items available at Riverside’s ‘country stores.’” *Id.*

²⁵ In one compounded cream scheme, for certain insurance plans, each tube of a scar cream led to payments of over \$20,000, and patients’ insurance plans were billed monthly over an extended period. Indictment at ¶ 85, *United States v. Adams*, No. 6:19-cr-00219 (N.D. Ala. Apr. 24, 2019).

²⁶ See, e.g., U.S. GOV’T ACCOUNTABILITY OFF., *supra* note 12, at 1 (noting that estimates vary, but the “most common is 10 percent”); *Gaming and the Health Care System: Trends in Health Care Fraud: Hearing Before the S. Special Comm. on Aging*, 104th Cong. 158 (1995) (Testimony of William J. Mahon, Executive Director, National Health Care Anti-Fraud Association) (citing a three percent to ten percent estimate for private payers) [hereinafter Testimony of William J. Mahon]; Donald M. Berwick & Andrew D. Hackbarth, *Eliminating Waste in U.S. Health Care*, 307 JAMA 1513, 1514 (2012) (addressing the financial impact of wasteful health care spending). See also *Criminal Prosecution as a Deterrent to Health Care Fraud: Hearing Before the Subcomm. on Crime & Drugs of the S. Comm. on the Judiciary*, 111th Cong. 64 (2009) (statement of Malcolm K. Sparrow, Professor of the Practice of Public Management, John F. Kennedy School of Government, Harvard University) (“The units of measure for losses due to health care fraud and abuse in this country are *hundreds of billions* of dollars per year. We just don’t know the first digit. It might be as low as *one* hundred billion. More likely *two* or *three*. Possibly *four* or *five*. But whatever that first digit is, it has eleven zeroes after it. These are staggering sums of money to waste, and the task of controlling and reducing these losses warrants a great deal of serious attention.”).

²⁷ *NHE Fact Sheet*, U.S. CTRS. FOR MEDICARE & MEDICAID SERVS. (Sept. 6, 2023, 4:57 PM), <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet>. The \$4.3 trillion comes out to approximately \$12,914 per person. *Id.*

²⁸ See, e.g., U.S. GOV’T ACCOUNTABILITY OFF., *supra* note 12, at 1 (noting that estimates vary, but the “most common is 10 percent,” and that kickbacks “cheat health insurance companies and programs out of billions of dollars annually”); H.R. REP. NO. 104-747, at 2 (1996) (“10% of every health care dollar spent in this Nation is lost to fraudulent and wasteful provider claims.”); U.S. DEP’T OF JUST., HEALTH CARE FRAUD REP. FISCAL YEAR 1994 [hereinafter DOJ HEALTH CARE FRAUD REPORT] (“While no one has an exact figure, the General Accounting Office estimates that health care fraud may account for as

of entire countries; for instance, in 2021, Mississippi’s gross domestic product (GDP) was \$127 billion and Wisconsin’s \$367 billion.²⁹ These GDPs are similar to the countries of Kenya and Malaysia respectively.³⁰

B. Kickbacks Cause Patient Harm

The harm does not end with overutilization and fraud. Patients are more likely to receive inappropriate, unnecessary, or lower quality care when a medical provider’s decision-making is poisoned by financial incentives.³¹ These unnecessary or lower quality services may not result in long-term physical harm to patients, but may take the form of the harm that naturally accompanies unnecessary care. These harms may include for instance, a delayed diagnosis, an unnecessary intrusion into a patient’s body, or the unnecessary discomfort that a patient often experiences from a procedure or treatment.³²

But it could take a more extreme form. Patients suffer—and indeed they sometimes die—when they receive treatments or procedures that are inappropriate or unnecessary.³³ As a Department of Justice report explained,

much as 10 [percent] of all health care expenditures.”); Testimony of William J. Mahon, *supra* note 26, at 158 (expressing that “health care fraud is an enormous and intolerable drain on both our private and public health care systems” and citing a three to ten percent estimate for private payers; Berwick & Hackbarth, *supra* note 26, at 1514 (addressing the financial impact of wasteful health care spending). That said, some have criticized the ten percent estimate as lacking an empirical basis. *See, e.g.*, Jerry L. Mashaw & Theodore R. Marmor, *Conceptualizing, Estimating, and Reforming Fraud, Waste, and Abuse in Healthcare Spending*, 11 YALE J. ON REG. 455, 459 (1994). Notably, however, many involved in investigating, prosecuting, and otherwise addressing health care fraud argue that even the ten percent estimate is overly conservative and that a higher percentage of health spending is lost to fraud. *See, e.g.*, WatchBlog, *Healthcare Fraud Schemes*, U.S. GOV’T. ACCOUNTABILITY OFF., at 4:26 (Feb. 24, 2016), <https://www.gao.gov/blog/2016/02/24/health-care-fraud-schemes-podcast>. Testifying to the Senate, former Attorney General Bill Barr, put the estimated percentage as high as fifteen percent. *Department of Justice Authorization for Fiscal Year 1993: Hearing Before the S. Comm. on the Judiciary*, 102nd Cong. 8 (1992) (Statement of William P. Barr, Att’y Gen. of the United States) (“Evidence suggests that professional criminals in the health-care business are looting as much as 15% of Americans’ \$800 billion health-care costs.”).

²⁹ Press Release, U.S. Dep’t of Comm., Bureau of Economic Analysis, Gross Domestic Product by State and Personal Income by State, 4th Quarter 2022 and Year 2022 (Mar. 31, 2023). The GDPs of many states are lower or within range of the low-end \$126 billion estimate, including South and North Dakota, both at approximately \$60 billion, New Mexico at \$109 billion, and Nebraska at \$161 billion. *Id.* at tbl.1.

³⁰ For instance, in 2022, Kenya’s GDP was \$113.42 billion and Malaysia’s was \$406.3 billion. *GDP* (current US\$), WORLD BANK, https://data.worldbank.org/indicator/NY.GDP.MKTP.CD?most_recent_value_desc=true (last visited Aug. 4, 2023).

³¹ Krause, *A Patient-Centered Approach*, *supra* note 11, at 582–83; Joan H. Krause, *Following the Money in Health Care Fraud: Reflections on a Modern-Day Yellow Brick Road*, 36 AM. J.L. & MED. 343, 352 (2010) [hereinafter Krause, *Following the Money*].

³² Krause, *Following the Money*, *supra* note 31, at 352.

³³ *See, e.g.*, DOJ HEALTH CARE FRAUD REPORT, *supra* note 28 (observing that health care fraud can result in unnecessary deaths); Lauren Hersch Nicholas, Caroline Hanson & Jodi B. Segal, *Association Between Treatment by Fraud and Abuse Perpetrators and Health Outcomes Among Medicare Beneficiaries*, 180 JAMA INTERNAL MED. 62, 66 (2020) (suggesting that quantitative study findings

“[k]ickbacks can lead to grossly inappropriate medical care, including unnecessary hospitalization, surgery, tests, and equipment.”³⁴

The following cases illustrate this concern. Purdue Pharmaceuticals and Insys Therapeutics Inc., both pharmaceutical companies that manufactured opioids, paid kickbacks to providers to encourage them to prescribe their opioid medications.³⁵ The overprescribing that resulted from these kickbacks resulted in patient addiction to opioids and deaths, which has contributed to the current United States opioid crisis.³⁶

The harm to patients extends outside of the opioid context. For instance, Dr. Farid Fata, a hematologist and oncologist, was convicted of prescribing chemotherapy and other treatments to patients who did not have cancer or who did not need those treatments, resulting in the death of several patients.³⁷ As part of his scheme, Dr. Fata then “forced” these misdiagnosed and mistreated patients—who, having been improperly treated for cancer, were now at death’s door—to go to a substandard home and hospice care facility because that entity was paying him kickbacks, causing them to suffer even more pain in their final days.³⁸ In another example, various entities paid Dr. Wilson Asfora kickbacks to use their medical devices in his spinal surgeries, resulting in the performance of unnecessary high-risk spinal surgeries that led to the paraparesis, a form of paralysis, of a patient.³⁹

support that “Medicare beneficiaries treated by known [fraud and abuse perpetrators] may be more likely to die and more likely to experience emergency hospitalization within 3 years after this exposure than a comparison group of beneficiaries”); Press Release, U.S. Dep’t of Just., Off. of Pub. Affs., Detroit Area Doctor Sentenced to 45 Years in Prison for Providing Medically Unnecessary Chemotherapy to Patients (July 10, 2015) [hereinafter Fata Sentencing Press Release] (noting that Dr. Fata created false cancer diagnoses and prescribed aggressive and dangerous treatments to defraud the government).

³⁴ DOJ HEALTH CARE FRAUD REPORT, *supra* note 28.

³⁵ Press Release, U.S. Dep’t of Just., Off. of Pub. Affs., Opioid Manufacturer Purdue Pharma Pleads Guilty to Fraud and Kickback Conspiracies (Nov. 24, 2020); Press Release, U.S. Dep’t of Just., Off. of Pub. Affs., Opioid Manufacturer Insys Therapeutics Agrees to Enter \$225 Million Global Resolution of Criminal and Civil Investigations (June 5, 2019).

³⁶ Fred Schulte, *How America Got Hooked on a Deadly Drug: An Inside Look at How Purdue Pharma Pushed OxyContin Despite Risks of Addiction and Fatalities*, KFF HEALTH NEWS (June 13, 2018), <https://kffhealthnews.org/news/how-america-got-hooked-on-a-deadly-drug/>.

³⁷ Fata Sentencing Press Release, *supra* note 33.

³⁸ The United States’ Sentencing Memorandum at 3, 34–37, *United States v. Fata*, No. 2:13-cr-20600 (E.D. Mich. May 28, 2015) (discussing kickbacks in the form of medical director fees and charitable donations). Victim impact statements described some of this conduct.

³⁹ Complaint at 69–70, *United States v. Asfora*, No. 4:16-cv-04115 (D.S.D. Aug. 12, 2016). The parties reached a settlement and jointly stipulated to the dismissal of the case. The United States’ Notice of Settlement at 1, *United States v. Asfora*, No. 4:16-cv-04115 (D.S.D. May 3, 2021); Joint Stipulation of Dismissal, *United States v. Asfora*, No. 4:16-cv-04115 (D.S.D. June 23, 2021). Very recently, there have been allegations that Medtronic, the world’s largest medical device company, was involved in a kickback conspiracy that resulted in an increase of amputations among patients who received care for vascular disease at the Veterans Affairs Medical Center in Wichita, Kansas. Annie Waldman, *Steak Dinners, Sales Reps and Risky Procedures: Inside the Big Business of Clogged Arteries*, PROPUBLICA (Feb. 16, 2023, 5:00 AM), <https://www.propublica.org/article/medtronic-medical-device-kickbacks-lawsuit-kansas>. The case is pending. *Schroeder v. Hutchinson*, Reg. Med. Ctr., No. 2:17-cv-2060 (D. Kan. Jan. 31, 2017).

C. Kickbacks Impede a Competitive Market

The harm from kickbacks goes further. Kickbacks can undermine the competitiveness of the health care market. They can “freeze competing suppliers from the system” by giving suppliers with lower-quality items or services a market advantage that has nothing to do with the quality of their product.⁴⁰ In the research market context, kickbacks can result in biased research. Some studies have found that “clinical research funded by manufacturers is not transparent and may be more likely to reach conclusions favorable to the sponsor than non-industry-sponsored studies.”⁴¹

The above-described harms warrant the special condemnation that kickbacks in the health care sector receive.

II. KICKBACK AND PAYMENT-FOCUSED LAWS

Recognizing the harms from kickbacks, Congress has passed several civil and criminal laws to scare off the devil, in a manner of speaking. These laws focus on discouraging or prohibiting payments that can cause healthcare providers to ground their judgment in a “baser, non-medical reason: making unauthorized money and lots of it,” instead of in their patients’ best interests and medical needs.⁴²

A. Civil Laws

On the civil side, these payment-focused laws are: (1) the Stark Law, (2) the Beneficiary Inducement Statute, and (3) the Physician Payment Sunshine Act (PPSA).⁴³

The Stark Law prohibits physician self-referrals for certain health services that may be paid for by Medicare or Medicaid.⁴⁴ Under the Stark Law, if a physician (or an immediate family member of a physician) has a

⁴⁰ United States v. Ruttenberg, 625 F.2d 173, 177 n.9 (7th Cir. 1980).

⁴¹ ABRAHAM GITTERMAN, DANIEL KRACOV, ALLISON SHUREN, ALAN REIDER, PAUL RUDOLF & LAUREN MILLER, WHAT IS . . . THE PHYSICIAN PAYMENTS SUNSHINE ACT OR “OPEN PAYMENTS”? 6 (2015) (citing Bodil Als-Nielson, Wendong Chen, Christian Gluud & Lise L. Kjaergard, *Association of Funding and Conclusions in Randomized Drug Trials: A Reflection of Treatment Effect or Adverse Events?*, 290 JAMA 921 (2003)); *id.* at 5 (“While the majority of [physician-manufacturer] relationships and interactions are beneficial to the continued innovation and improvement of America’s healthcare system, some have expressed concern that ‘payments from manufacturers to physicians and teaching hospitals can also introduce conflicts of interests that may influence research, education, and clinical decision-making in ways that compromise clinical integrity and patient care, and may lead to increased health care costs.’” (quoting Medicare, Medicaid, Children’s Health Insurance Programs; Transparency Reports and Reporting the Physician Ownership or Investment Interests, 42 C.F.R. 9458, 9518 (Feb. 8, 2013))). *See also* Anders Jørgensen, Jørgen Hilden & Peter C. Gøtzsche, *Cochrane Reviews Compared with Industry Supported Meta-Analyses of the Same Drugs: Systematic Review*, 333 BRIT. MED. J. 782 (2003) (analyzing bias in industry-supported drug reviews).

⁴² United States v. Howard, 28 F.4th 180, 207 (11th Cir. 2022).

⁴³ Codified at 42 U.S.C. § 1395nn, 42 U.S.C. § 1320a-7a(a)(5), and 42 U.S.C. § 1320a-7h, respectively.

⁴⁴ 42 U.S.C. § 1395nn(a); *see also* HHS-OIG Fraud & Abuse Laws, *supra* note 7.

“financial relationship” with an entity, the physician may not make a referral to the entity for the furnishing of twelve specified health services for which payment may be made under Medicare or Medicaid.⁴⁵ Further, the entity may not bill Medicare or Medicaid or any individual or entity for services furnished pursuant to a prohibited referral.⁴⁶ In addition to being a civil tool, the Stark Law differs from the Anti-Kickback Statute in several respects, including that it is limited to physicians and immediate family members, and is limited to physician referrals for services paid for by Medicare and Medicaid.⁴⁷

The Beneficiary Inducement Statute focuses specifically on payments to beneficiaries.⁴⁸ It prohibits an individual or entity from providing remuneration to patients who are eligible for Medicare or Medicaid benefits if that individual or entity knows (or should know) that doing so is likely to influence the patient’s decision to order or receive items or services from a particular provider.⁴⁹ As with the Stark Law, it is limited to Medicare and Medicaid.⁵⁰

The PPSA does not prohibit payments, but rather seeks to discourage improper payments by requiring they be reported and made publicly available.⁵¹ It requires manufacturers of drugs, medical devices, and biological and medical supplies that manufacture one or more products that are covered by Medicare, Medicaid, or the Children’s Health Insurance Program⁵² to collect and report to the Centers for Medicare and Medicaid Services (CMS) financial relationships with physicians, teaching hospitals, and various other providers.⁵³ It also requires these manufacturers, as well

⁴⁵ The specified health services are referred to as “designated health services,” and include clinical laboratory services, physical therapy services, among others. 42 U.S.C. § 1395nn(h)(6).

⁴⁶ 42 U.S.C. § 1395nn(a).

⁴⁷ 42 U.S.C. § 1395nn(a); HHS-OIG Fraud & Abuse Laws, *supra* note 7. This is unlike the Anti-Kickback Statute, which applies to all federal health benefit programs, including Medicare, Medicaid, and also TRICARE. 42 U.S.C. 1320a-7b(b), (f). As with the criminal kickback laws, the Stark Law exempts certain conduct. *See* 42 U.S.C. § 1395nn(b)–(e) (enumerating the Stark Law statutory safe harbors).

⁴⁸ 42 U.S.C. § 1320a-7a(a)(5). The Beneficiary Inducement Statute is part of the Civil Monetary Penalties Law (CMPL), a law allowing the government to seek civil monetary penalties and exclusion for fraudulent conduct.

⁴⁹ *Id.* *See also* OFF. OF INSPECTOR GEN., SPECIAL ADVISORY BULLETIN: OFFERING GIFTS AND OTHER INDUCEMENTS TO BENEFICIARIES (Aug. 2002) (explaining that offering kickbacks may make a party liable for civil penalties).

⁵⁰ 42 U.S.C. § 1320a-7a(a)(5).

⁵¹ 42 U.S.C. § 1320a-7h(a); *Law and Policy*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Jan. 23, 2023, 2:18 PM), <https://www.cms.gov/OpenPayments/Law-and-Policy>. For a more fulsome discussion (and critique) of the PPSA, see Jacob T. Elberg, *Ain’t No Sunshine: Bringing Physician Conflicts Out of the Dark*, U. RICH. L. REV. (forthcoming) (manuscript at *9–18) (on file with author).

⁵² In practice, the PPSA covers a large swath of manufacturers since the products provided by those manufacturers are also paid for by private payers. *See* Elberg, *supra* note 51, at *13–14.

⁵³ 42 U.S.C. § 1320a-7h(a)(1)(A), (e)(6). The various other providers are physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants, and certified nurse-midwives. The PPSA came into existence with the passage of the

as group purchasing organizations (groups that purchase, arrange for, or negotiate the purchase of drugs and other products), to disclose any physician ownership or investment interests held in the applicable manufacturer or group purchasing organization.⁵⁴ CMS then makes the information available through a publicly searchable database.⁵⁵

None of these civil laws prohibit kickbacks paid for referrals of items or services paid for by private payers. That said, the PPSA does at least seek to shine a light on these payments by requiring that they be disclosed—assuming that the payment is made by a covered entity.⁵⁶

B. *Criminal Laws*

Importantly, for purposes of this Article, on the criminal side, the payment-focused laws are: (1) the Anti-Kickback Statute, and (2) the Eliminating Kickbacks in Recovery Act (EKRA).⁵⁷ As their names suggest, both are kickback laws, and although they differ in significant respects, they are similar in that they both apply to anyone involved in the conduct in question (providers, sales representatives, beneficiaries, etc.).⁵⁸

The Anti-Kickback Statute makes it a felony for a person to knowingly and willfully offer, pay, solicit, or receive anything of value (referred to in the statute as “remuneration”), directly or indirectly, to induce referrals of “any item or service” reimbursable under a federal health care program.⁵⁹ The statute prohibits both the offer or payment of remuneration for patient referrals, as well as the offer or payment of anything of value in return for purchasing, leasing, ordering, or arranging for, or recommending the purchase, lease, or ordering of any item or service that is reimbursable by a federal health care program.⁶⁰ In a nutshell, it prohibits paying, receiving, offering, and soliciting kickbacks for items or services to be paid for by federal health care programs.

Like the Anti-Kickback Statute, EKRA prohibits the offer or payment and the solicitation or receipt of remuneration.⁶¹ However, it is both narrower and broader in some respects than the Anti-Kickback Statute. It is narrower because it applies only to a limited set of (arguably) opioid

Affordable Care Act in 2010. It initially only addressed payments to physicians and teaching hospitals. In January 2021, it began applying to the other types of providers as well.

⁵⁴ 42 U.S.C. § 1320a-7h(a)(2).

⁵⁵ 42 U.S.C. § 1320a-7h(c).

⁵⁶ Elberg, *supra* note 51, at *12–15.

⁵⁷ Codified at 42 U.S.C. § 1320a-7b(b) and 18 U.S.C. § 220, respectively.

⁵⁸ 42 U.S.C. § 1320a-7b(b); 18 U.S.C. § 220.

⁵⁹ 42 U.S.C. § 1320a-7b(b)(1)(A).

⁶⁰ 42 U.S.C. § 1320a-7b(b).

⁶¹ 18 U.S.C. 220(a), (e)(3) (referring to and defining “health care benefit program”); 18 U.S.C. § 24(b) (defining “health care benefit program” as “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.”).

addiction related services; specifically it applies to referrals “to a recovery home, clinical treatment facility, or laboratory.”⁶² It is broader because it applies to a greater number of health care programs and applies to government-funded programs as well as private pay health care programs.⁶³ Thus, EKRA makes it a felony to knowingly and willfully solicit, receive, offer, or pay remuneration, directly or indirectly, referring a patient to, or in exchange for, an individual using the services of, a recovery home, clinical treatment facility, or laboratory with respect to services covered by any health care benefit program.⁶⁴

Both statutes have safe harbor provisions, i.e., provisions that shelter certain payment and business practices that are believed to be beneficial but are implicated by the Anti-Kickback Statute from criminal and civil prosecution under the Anti-Kickback Statute.⁶⁵ Examples include safe harbors for investment interests in publicly traded companies and small private entities, renting and leasing of space, and employee compensation arrangements.⁶⁶

1. *The Statutory Text of the Anti-Kickback Statute and EKRA*

In relevant part, the Anti-Kickback Statute states:

(1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring 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) in return for purchasing, leasing, ordering, or arranging for or recommending 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*,

⁶² 18 U.S.C. § 220(a)(1). The word “arguably” is used because as discussed in the next section, EKRA does not limit “laboratories” to laboratories testing for controlled substances or substances related to opioid addiction.

⁶³ 18 U.S.C. § 220(a).

⁶⁴ *Id.*

⁶⁵ Safe harbors shelter certain payment and business practices that are believed to be beneficial but are implicated by the Anti-Kickback Statute from criminal and civil prosecution under the statute. They therefore seek to accommodate concerns that these laws might stifle innovation. *See* 42 U.S.C. § 1320(a)–7b(b)(3) (AKS statutory safe harbors); 42 C.F.R. § 1001.952 (AKS regulatory safe harbors); 18 U.S.C. § 220(b) (EKRA statutory safe harbors).

⁶⁶ 42 U.S.C. § 1320a-7b(b)(3); 18 U.S.C. § 220(b).

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$100,000 or imprisoned for not more than 10 years, or both.

(2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

(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*,

shall be guilty of a felony[.]⁶⁷

The Anti-Kickback Statute defines a “federal health care program” as “any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government” or State health care programs such as Medicaid that receive federal funds.⁶⁸

In relevant part, EKRA provides:

[W]hoever, with respect to services covered by a *health care benefit program*, in or affecting interstate or foreign commerce, knowingly and willfully—

(1) solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return *for referring a patient or patronage to a recovery home, clinical treatment facility, or laboratory*; or

(2) pays or offers any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory; or

⁶⁷ 42 U.S.C. § 1320a-7b(b)(1)–(2) (emphasis added).

⁶⁸ 42 U.S.C. § 1320a-7b(f). Note, however, that the Anti-Kickback Statute does not protect federal employee health benefit plans or plans on the Affordable Care Act exchanges, even though both are provided federal funds. See Diké-Minor, *supra* note 6, at 146, 152–53.

(B) in exchange for an individual using the services of that *recovery home, clinical treatment facility, or laboratory,*

shall be fined not more than \$200,000, imprisoned not more than 10 years, or both, for each occurrence.⁶⁹

EKRA defines a “health care benefit program” as “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.”⁷⁰ In addition, EKRA defines “recovery home” and “clinical treatment facility” as limited to services involving the treatment of substance abuse,⁷¹ but adopts a general definition of “laboratory” that, at least based on the text of the statute, need not be limited to only laboratory services for substance abuse.⁷² The differences between the Anti-Kickback Statute and EKRA will be discussed in more detail in Part IV.A.

2. *The Anti-Kickback Statute’s Breadth*

The Anti-Kickback Statute is broad in many ways, except in one significant way: its protections do not extend to private payers, which this Article argues they should. Examples of the ways in which it is broad are:

- It criminalizes the offering and soliciting, not just the paying and receiving, of kickbacks.⁷³
- It addresses payments to “any person.” The person in question does not have to be the provider or have the ultimate power over the referral decision.⁷⁴
- It covers “any remuneration,” not just monetary payments, and accordingly, applies to services or any other types of compensation.⁷⁵ And it covers

⁶⁹ 18 U.S.C. § 220(a) (emphasis added).

⁷⁰ 18 U.S.C. § 220(e)(3); 18 U.S.C. § 24(b).

⁷¹ 18 U.S.C. § 220(e)(2), (5).

⁷² 18 U.S.C. § 220(e)(4).

⁷³ 42 U.S.C. § 1320a-7b(b)(1)–(2). *See also* MICHAEL K. LOUCKS, PROSECUTING AND DEFENDING HEALTH CARE FRAUD CASES ch. 6, § 6.III.A (2021), (ebook), <https://www.bloomberglaw.com/product/blaw/document/28208706600>.

⁷⁴ 42 U.S.C. § 1320a-7b(b)(2). *See also* United States v. Shoemaker, 746 F.3d 614, 629 (5th Cir. 2014) (“Contrary to the district court’s opinion and the parties’ submissions, we did not hold in [a prior case] that a payee with ‘relevant decisionmaker’ status is an independent, substantive requirement of the statute. Such a novel move would be tantamount to re-writing the statutory text, which, as noted above, criminalizes payments to ‘any person[s],’ so long as they are made with the requisite intent.”) (citations omitted); United States v. Polin, 194 F.3d 863, 866–67 (7th Cir. 1999) (“The different subsections [(A) and (B)] do not distinguish between physicians and lay-persons.”).

⁷⁵ 42 U.S.C. § 1320a-7b(b)(1)–(2).

remuneration whether made directly or indirectly, or “in cash or in kind.”⁷⁶

- Subsection (2)—which addresses the offering or paying of kickbacks—does not require proof that something was actually referred in exchange for the remuneration.⁷⁷ The crime is complete once the payer offers or pays remuneration *even if* the payee never makes a referral.⁷⁸
- It “does not require proof of a loss to the federal health care program.”⁷⁹
- It applies even when medical services were for legitimate reasons if a non-de minimis purpose of the payments was to induce referrals of such services.⁸⁰

Notwithstanding this otherwise broad scope, the Anti-Kickback Statute exempts private payers from its protections.⁸¹

III. CONGRESS SHOULD EXPAND THE ANTI-KICKBACK STATUTE TO PROTECT PRIVATE PAYERS

Using its authority under the Commerce Clause, Congress should extend the Anti-Kickback Statute’s protections to private payers.⁸² This Part sets out the arguments for doing so, namely: (1) kickback harms also affect private payers, and any unique harms can be addressed through sentencing enhancements; (2) the “private payers are managed care” rationale that Congress has provided in declining to expand the Anti-Kickback Statute is an insufficient justification; and (3) the narrow reach of the Anti-Kickback Statute harms prosecutors’ ability to address health care fraud.

A. Kickback Harms Also Affect Private Payers

The harms from kickbacks—overutilization, patient harm, and impeding a competitive market—occur regardless of whether a patient is covered by

⁷⁶ *Id.*; United States v. Goldman, 607 F. App’x 171, 174 (3d Cir. 2015) (“Remuneration means [p]ayment or compensation. . . . The statute’s prohibition is broad: physicians may not accept ‘any’ payment in exchange for referrals. Nor does the law limit ‘remuneration’ by the type or source of the payment.”) (internal quotation marks and citations omitted).

⁷⁷ 42 U.S.C. 1320a-7b(b)(2).

⁷⁸ LOUCKS, *supra* note 73, at ch. 6 § 6.III.A.

⁷⁹ *Id.* (citing United States v. Baystate Ambulance & Hosp. Rental Serv., 874 F.2d 20, 32 n.21 (1st Cir. 1989)).

⁸⁰ LOUCKS, *supra* note 73, at ch. 6 § 6.III.B.1.

⁸¹ See *supra* Part I.

⁸² Congress should address any interstate nexus concerns by using the same definition for health insurance plans used in EKRA and the Criminal Health Care Fraud Statute. As noted, 18 U.S.C. § 24(b) defines a “health care benefit program” as “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.”

private or government health insurance. Indeed, it is possible, given that approximately seventy percent of Americans are on private health insurance plans, that these harms may have a greater impact on private payers and their beneficiaries.⁸³

1. *Overutilization and Fraud*

i. Private Health Insurance Plans Are Also Vulnerable to Overutilization and Fraud

To echo the infamous bank robber Willie Sutton, fraudsters go “where the money is.”⁸⁴ This would include all insurance plans, whether public or private; fraudsters do not usually single out government health insurance plans to defraud.⁸⁵ Stated differently, there is no question that “[b]oth public health insurance programs and private health insurers are vulnerable to fraud and abuse.”⁸⁶ This fact is borne out by the cases that have been charged.⁸⁷

⁸³ ROSSO, *supra* note 2.

⁸⁴ *United States v. Sanjar*, 876 F.3d 725, 733 (5th Cir. 2017) (“The reason Willie Sutton once gave for robbing banks is true of Medicare today: that’s where the money is.”). Willie Sutton was an American bank robber with an extensive criminal career. *See Willie Sutton*, FBI, <https://www.fbi.gov/history/famous-cases/willie-sutton> (last visited Aug. 7, 2023). Some version of this quote has shown up in multiple discussions about health care fraud. *See, e.g.*, 140 CONG. REC. S26003 (daily ed. Sept. 27, 1994) (statement of Sen. Cohen: “Just as Willie Sutton said he robbed banks because ‘that’s where the money is,’ many scam artists seek out health care fraud because they know that the health care budget provides one of the biggest pots of money available for the taking—and one that has very little chance of them being caught.”); *Gaming the Health Care System: Trends in Health Care Fraud, Hearing Before the S. Special Comm. on Aging*, 104th Cong. 194 (1995) (statement of the Ass’n of the Am. Physicians & Surgeons, Inc.) (“Willie Sutton robbed banks because ‘that’s where the money is.’”); Pamela H. Bucy, *Crimes by Health Care Providers*, 1996 U. ILL. L. REV. 589, 589; Krause, *Following the Money*, *supra* note 31, at 344.

⁸⁵ There are instances where fraudsters target government (or other) health care programs exclusively. This occurs for instance, where those programs present unique opportunity for fraud, due to some quirk of their payment systems. For instance, between 2014 and 2015, compounding fraud primarily targeted TRICARE. *See* Evan Sweeney, *Fierce Exclusive: After Explosion of Compounded Drug Fraud, Legal Experts Say Party’s Over*, FIERCE HEALTHCARE (Mar. 2, 2016, 2:19 PM), <https://www.fiercehealthcare.com/antifraud/fierce-exclusive-after-explosion-compounded-drug-fraud-legal-experts-say-party-s-over>. However, as evidenced by multiple subsequent prosecutions, this fraud did not focus exclusively on TRICARE. *See, e.g.*, Press Release, U.S. Att’y’s Off., N.D. Ala., Multiple, *supra* note 21 (discussing a compounding fraud scheme that targeted private and public payers). Fraudsters may also specifically target a program such as Medicare based on the perceived forgetfulness of its beneficiaries, using that to the advantage of the scheme.

⁸⁶ *See* U.S. GOV’T ACCOUNTABILITY OFF., *supra* note 12, at 4.

⁸⁷ *See, e.g.*, *Health Care Waste, Fraud, and Abuse: Hearing Before the Subcomm. on Health of the H. Comm. on Ways & Means*, 105th Cong. 76, 81 (1997) (prepared statement of Charles L. “Chuck” Owens, Chief, Financial Crimes Section, FBI) (providing a table stating that private insurance programs account for forty percent of FBI caseload); Press Release, U.S. Att’y’s Off., S.D. Fla., Miami Doctor Sentenced to Federal Prison for Committing \$38 Million Health Care Fraud Scheme, Spending Proceeds on Beachfront Condos and Luxury Vehicles (Aug. 3, 2022) (\$38 million fraud infusion scheme targeting Blue Cross Blue Shield and United Healthcare); Press Release, U.S. Att’y’s Off., National Health Care Fraud Enforcement Action Results in Charges of Over \$308 Million in Intended Loss Against 52 Defendants in the Southern District of Florida (Sept. 17, 2021) (various schemes against various private payers); Press Release, U.S. Dep’t of Just., Off. of Pub. Affs., DOJ Announces Coordinated Law Enforcement Action to Combat Health Care Fraud Related to COVID-19 (May 26, 2021) (\$10 million COVID-19 testing fraud targeting Blue Cross Blue Shield of Louisiana, Medicare, and Medicaid); Press

As discussed below, it also has been repeatedly acknowledged by multiple government agencies, private groups, and Congress.

For instance, in 1992 the United States Government Accountability Office (GAO) reported that “[h]ealth care fraud has expanded beyond single health care provider frauds to organized activity affecting health care programs in both the government and private insurance sectors.”⁸⁸ In another report nearly a year later, it emphasized that “the threat of insurance fraud and abuse is endemic, not just to Medicare, but to the entire health care system.”⁸⁹ A 1993 joint multi-federal agency announcement was even more explicit as to kickbacks, stating that “there is no reason to believe that the overutilization risk attributable to kickbacks does not apply to private payers. Most kickback schemes involve federal programs and private payers as well[.]”⁹⁰ Similarly, the Department of Justice stated in a 1995 report that “[p]erpetrators of health care fraud rarely infiltrate just one health care system or limit their fraud solely to public health care systems.”⁹¹ The head of the Federal Bureau of Investigation’s Financial Crimes Unit confirmed this, stating “[i]t is the rule rather than the exception that those engaged in committing health care fraud do not discriminate against any particular health care plan.”⁹² Indeed, recognizing this reality, CMS created the Healthcare Fraud Prevention Partnership, a partnership between federal and state agencies, private insurers, states, and associations to exchange information and best practices across the public and private sectors in order to prevent and detect health care fraud.⁹³

Private groups have also acknowledged this vulnerability. In testimony to Congress, the Executive Director of the National Health Care Anti-Fraud Association (NHCAA), a private-public partnership against health care fraud, stated that “almost never do fraudulent providers defraud either the

Release, U.S. Att’y’s Off., N.D. Ala., Multiple, *supra* note 21 (\$50 million compounding drug scheme targeting Blue Cross Blue Shield and Alabama and other insurance plans); Press Release, U.S. Att’y’s Off., N.D. Ala., Huntsville Pill Mill Doctor Sentenced to 15 Years in Prison for Illegal Prescribing and Health Care Fraud (Feb. 27, 2017) (\$9.5 million urine testing fraud scheme targeting Blue Cross Blue Shield of Alabama and Medicare).

⁸⁸ U.S. GOV’T ACCOUNTABILITY OFF., *supra* note 12, at 2.

⁸⁹ U.S. GOV’T ACCOUNTABILITY OFF., GAO/HRD-93-6, MEDICARE CLAIMS 8 (1992).

⁹⁰ H.R. REP. NO. 104-747, at 3, 8 (1996) (quoting the 1993 HHS/OMB/DOJ press release titled “Administration Announces Task Force Recommendations to Combat Health Care Fraud and Abuse,” and citing the press release as available in subcommittee files).

⁹¹ DOJ HEALTH CARE FRAUD REPORT, *supra* note 28.

⁹² *Health Care Waste, Fraud, and Abuse: Hearing Before the Subcomm. on Health of the Comm. on Ways and Means*, 105th Cong. 97 (Oct. 9, 1997) (reply of Charles L. “Chuck” Owens, Chief, Financial Crimes Section, FBI).

⁹³ Press Release, U.S. Dep’t of Just., Off. of Pub. Affs., Fact Sheet: The Health Care Fraud and Abuse Control Program Protects Consumers and Taxpayers by Combating Health Care Fraud (Feb. 26, 2016); *see also HFPP: About the Partnership*, U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/hfpp/about> (last visited Aug. 10, 2023). The program’s partners also include federal and state agencies, law enforcement, private health insurance plans, employer organizations, and health care anti-fraud associations. *Current HFPP Partners*, U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/hfpp/about/current-partners> (last visited Aug. 17, 2023).

private or public sector exclusively.”⁹⁴ Indeed, he went on to explain that the “only smart way to commit health care fraud is to spread your activity among enough payers, so that you remain relatively inconspicuous with each one for the longest possible time.”⁹⁵ In subsequent testimony, he stated “you almost never find someone defrauding the private or the public sector exclusively. Generally, if they defraud Medicare, Medicaid, [] and so on, they are defrauding private payers and vice versa.”⁹⁶

Congressional committees have acknowledged the same, with one looking specifically at this issue stating, “public and private payers share the same vulnerability to abusive practices and fraud.”⁹⁷

ii. The Costs of Fraud Get Passed on to All Americans

The massive amount of unnecessary spending caused by fraud has broader consequences. It drives up the cost of health care for all Americans regardless of their source of health insurance (or lack thereof) and results in consumers paying higher premiums, increased deductibles, and increased copayments.⁹⁸ As the GAO explained, everyone—beneficiaries, employers, and taxpayers—pays the price for overutilization and fraud:

[B]eneficiaries who pay more in premiums for medical services and equipment and in their copayments or contributions; businesses who are compelled to pay increasing amounts to provide health care to their employees; and taxpayers who pay more to cover health care expenditures in public health plans.⁹⁹

⁹⁴ *Keeping Fraudulent Providers Out of Medicare and Medicaid: Hearing Before the Subcomm. on Hum. Res. and Intergov. Rels. of the H. Comm. on Gov't Reform & Oversight*, 104th Cong. 81 (1996) (testimony of William J. Mahon, Executive Director of the National Health Care Anti-Fraud Association).

⁹⁵ *Id.*

⁹⁶ *Gaming the Health Care System: Trends in Health Care Fraud: Hearing Before the S. Spec. Comm. on Aging*, 104th Cong. 141 (1995) (statement of William Mahon, Executive Director, National Health Care Anti-Fraud Association). *See also id.* at 158 (testimony of William J. Mahon, Executive Director of the National Health Care Anti-Fraud Association) (noting that private insurance plans estimated fraud to be between three percent to ten percent of spending).

⁹⁷ H.R. REP. NO. 104-747, at 7 (1996).

⁹⁸ KONGSTVEDT, *supra* note 1, at 16 (“As health care costs increase, so does the cost of insurance coverage.”). In many ways, the harmful effects of fraud are simply a variation of the classic cost-shifting problem that plagues the United States health system and that inspired the creation of the Individual Mandate—the requirement that most Americans purchase health insurance—in the 2010 Affordable Care Act. *See Nat'l Fed'n Indep. Bus. v. Sebelius*, 567 U.S. 519, 547 (2012) (“To recoup the losses [from care for the uninsured], hospitals pass on the cost to insurers through higher rates, and insurers, in turn, pass on the cost to policy holders in the form of higher premiums.”).

⁹⁹ U.S. DEP'T OF JUST., HEALTH CARE FRAUD REP. FISCAL YEARS 1995 & 1996 8 (1997), <https://www.justice.gov/archives/opa/us-department-justice-health-care-fraud-report-fiscal-years-1995-1996>. *See also* LOUCKS, *supra* note 73, at ch. 6, § 6.II.B (“If a person or entity receives payments for referring [insured] patients to purchase particular insured items or services, then not only will the medical referral decision not be made with the patient's best interests in mind, but also the overall cost of health care to the [insurance] program will be driven up by the payment of referral fees and by the referral of

Members of Congress have noted the same, observing that fraud against private insurers ultimately gets passed on to all taxpayers because it causes health care costs and premiums to increase.¹⁰⁰ Taxpayers may not pay directly for the fraud by funding these government health insurance plans, but they pay indirectly by virtue of the increased costs of health care.¹⁰¹

iii. Unique Harms to Government-Funded Health Programs Can be and Are Addressed Through Sentencing Enhancements

Although overutilization and fraud harm all insurance plans, they can cause unique harms to government-funded health insurance plans. Overuse of these plans, which provide insurance to vulnerable populations, “diverts from those most in need, the nation’s elderly and poor, scarce program dollars that were intended to provide vitally needed quality health services.”¹⁰² This in turn impacts the financial stability of the state and local budgets that help fund some of these programs.¹⁰³

However, addressing these unique harms does not require that Congress ignore the harms that kickbacks cause to private health care payers. These special harms can be addressed through sentencing enhancements.¹⁰⁴ Indeed, Section 2B1.1 of the United States Sentencing Guidelines provides for a three-tiered enhancement to a defendant’s offense level—which determines the defendant’s advisory sentencing range—when a health care offense involves loss to a “Government health care program.”¹⁰⁵ It states that if the defendant was convicted of a Federal health care offense involving these programs, his or her offense level should be increased by two levels if the loss exceeds \$1 million, three levels if the loss exceeds \$7 million, and four levels if the loss exceeds \$20 million.¹⁰⁶ “Federal health care offenses” include violations of the Anti-Kickback Statute.¹⁰⁷ This or a similar

patients for care that they do not need.”) (citations omitted). Some studies have also shown that physician interactions with industry are linked to a greater willingness to prescribe newer, more expensive drugs. *See, e.g.*, Chren & Landefeld, *supra* note 20, at 684; Watkins et al., *supra* note 20, at 1178; Wazana, *supra* note 20, at 373.

¹⁰⁰ *Health Care Fraud: Hearing Before the S. Comm. on the Judiciary*, 103rd Cong. 1, 3 (1994) (opening statement of Sen. Joseph Biden, Chairman of S. Comm. on the Judiciary & statement of Sen. Herbert Kohl, Member, S. Comm. on the Judiciary); H.R. REP. NO. 104-747, at 2 (1996) (“[T]he general public . . . pay[s] the price for health care fraud in the form of higher insurance premiums and higher costs for Government health programs.”).

¹⁰¹ H.R. REP. NO. 104-747, at 2 (1996).

¹⁰² H.R. REP. NO. 95-393, at 44 (1977).

¹⁰³ *Id.*

¹⁰⁴ *See, e.g.*, U.S. SENT’G GUIDELINES MANUAL, ch. 3 (U.S. SENT’G COMM’N 2021) (discussing various adjustments including enhancements).

¹⁰⁵ Defined as “any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by federal or state government.” U.S. SENT’G GUIDELINES MANUAL § 2B1.1 (U.S. SENT’G COMM’N 2021). The Commentary adds that “[e]xamples of such programs are the Medicare program, the Medicaid program, and the CHIP program.” *Id.* The ACA directed the U.S. Sentencing Commission to create this enhancement. Affordable Care Act, Pub. L. No. 111-148, § 10606(a)(2), 124 Stat. 119 (2010).

¹⁰⁶ U.S. SENT’G GUIDELINES MANUAL § 2B1.1 (U.S. SENT’G COMM’N 2021).

¹⁰⁷ 18 U.S.C. § 24.

enhancement could be used to address any unique harms to government-funded health care plans.

2. Patient Harm

i. Patients with Private Health Insurance Also Suffer Harm from Kickbacks

As discussed in Part I, patients are more likely to receive inappropriate, unnecessary, or lower quality care when a provider's decision making is poisoned by financial incentives.¹⁰⁸ This harm can be less extreme (e.g., an unnecessary intrusion into a patient's body) or more extreme (e.g., serious suffering and/or death).¹⁰⁹ There is no reason to believe these harms are limited to patients with government health insurance.

Indeed, by passing EKRA, Congress recognized that kickbacks result in harm to patients with private health insurance.¹¹⁰ In her comments in support of EKRA, Senator Amy Klobuchar, who co-sponsored the bill in the Senate, stated that the goal of the bill was to “go after the bad guys, the people who are trying to get people hooked on these drugs.”¹¹¹

EKRA does not adequately address the harm to patients, however, because although kickbacks can result in significant patient harm in opioid-related cases, they can also cause harm in non-opioid cases. The conduct of Dr. Fata and Dr. Asfora (discussed in Part I), among others, makes that clear. To be sure, this Article is not arguing that these kickback opioid-related harms should not be addressed by the kickback laws. It argues only that other patient harms should be as well.

ii. Additional Harms to Patients from Opioid-Related Conduct Can Be and Are Addressed Through the Vulnerable Victim Sentencing Enhancements

As with fraud against government payers, additional harms to patients stemming from opioid-related conduct can be addressed through a sentencing enhancement, specifically the vulnerable victim sentencing enhancements, Sections 2D1.1(b)(16)(B) and 3A1.1(b) and of the United States Sentencing Guidelines.¹¹²

¹⁰⁸ See DuBois et al., *supra* note 22, at 30; Krause, *Following the Money*, *supra* note 31, at 352; Krause, *A Patient-Centered Approach*, *supra* note 11, at 582–83, 587–95.

¹⁰⁹ See *supra* Part I.B.

¹¹⁰ Diké-Minor, *supra* note 6, at 159 (discussing the passage of EKRA).

¹¹¹ 164 CONG. REC. S6472–73 (daily ed. Oct. 3, 2018) (statement of Sen. Amy Klobuchar).

¹¹² U.S. SENT'G GUIDELINES MANUAL §§ 3A1.1(b), 2D1.1(b)(16)(B) (U.S. SENT'G COMM'N 2021). These harms are also addressed by other laws. The law that is most often used to prosecute providers who prescribe controlled substances without a legitimate medical purpose is 21 U.S.C. § 841(a). It makes it a federal crime, “[e]xcept as authorized,” for any person knowingly or intentionally “to manufacture, distribute, or dispense a controlled substance,” such as opioids. See also *Ruan v. United States*, 142 S. Ct. 2370, 2374–75 (2022) (discussing the statute and intent standard). This statute is used to prosecute street drug dealers but also doctors who prescribe these substances to their patients without “authority.”

The Section 2D1.1 two-level enhancement applies when the defendant plays a leading role as an organizer, leader, manager, or supervisor in a drug offense that involves the distribution of a controlled substance to a person “unusually vulnerable due to physical or mental condition or otherwise particularly susceptible to the criminal conduct.”¹¹³ Some courts have held that it therefore applies when a person exploits drug addictions as part of a crime.¹¹⁴

The Section 3A1.1(b) two-level enhancement applies “[i]f the defendant knew or should have known that a victim of the offense was a vulnerable victim,” and another two-levels apply if the “offense involved a large number of vulnerable victims.”¹¹⁵ The Commentary to the Guidelines defines a vulnerable victim as a person who is “unusually vulnerable due to age, physical or mental condition, or who is otherwise particularly susceptible to the criminal conduct.”¹¹⁶ Courts have held that this enhancement applies when the victims are addicted to drugs if other factors suggesting great reliance on the defendant are present.¹¹⁷

3. *Impeding a Competitive Market*

As noted, kickbacks can negatively impact a competitive market because they “freeze competing suppliers from the system” by giving suppliers with lower-quality items or services a market advantage that has nothing to do with the quality of the product.¹¹⁸ Ensuring a competitive market is of even more importance in the private space. If we are to rely on the private space to provide affordable health care, then it becomes paramount that the market functions properly and is not contaminated by kickbacks.

B. *The “Private Plans are Managed Care Plans” Rationale Falls Short*

This section sets out the second argument for expanding the Anti-Kickback Statute to private payers. It explains that Congress relied on a “private plans are managed care plans” rationale when it declined to do so. This section proceeds by describing the articulation of this rationale and then explains why it fails to justify the exclusion of private plans from the Anti-Kickback Statute’s protections.

i.e., without a legitimate medical purpose and outside of the usual course of professional practice. 21 C.F.R. § 1306.04(a) (2021).

¹¹³ U.S. SENT’G GUIDELINES MANUAL §§ 3B1.1, 2D1.1(b)(16)(B) (U.S. SENT’G COMM’N 2021).

¹¹⁴ See, e.g., *United States v. Goduto*, 568 Fed. App’x. 843, 845 (11th Cir. 2014) (upholding a lower court decision applying the sentencing guidelines to drug exploitation); *United States v. Sanchez*, 807 Fed. App’x 950, 951–52 (11th Cir. 2020) (citing the patient’s overdose history as a justification for applying the enhancement).

¹¹⁵ U.S. SENT’G GUIDELINES MANUAL § 3A1.1(b) (U.S. SENT’G COMM’N 2021).

¹¹⁶ *Id.* at § 3A1.1 cmt. n.2.

¹¹⁷ See, e.g., *United States v. Salahmand*, 651 F.3d 21, 30 (D.C. Cir. 2011) (applying the enhancement when parties are affected by the defendant’s underlying conduct).

¹¹⁸ *United States v. Rutenberg*, 625 F.2d 173, 177 n.9 (7th Cir. 1980).

1. *The Story of the “Private Plans are Managed Care Plans” Rationale*

At its creation in 1972, the Anti-Kickback Statute applied only to Medicare and Medicaid.¹¹⁹ In the early to mid-1990s, Congress made multiple unsuccessful—but bipartisan—efforts during the President Clinton health care reform era to expand the Anti-Kickback Statute’s protections to private payers.¹²⁰ These efforts received strong support from law enforcement and the private insurance industry.¹²¹ Over the course of multiple hearings and reports, representatives of the Federal Bureau of Investigation, Department of Justice, the NHCAA called for an expansion.¹²²

These efforts ultimately failed because although there was bi-partisan support for the kickback (and broader fraud) reforms, there was not bipartisan support for the broader health care reforms that then-President Clinton wanted.¹²³ Further, efforts to extract the fraud reform from the larger health reform efforts failed based on concerns that the broader reform efforts would lose support without the fraud provisions.¹²⁴

In 1996, however, after the Clinton Administration’s broader health care reforms failed, Congress passed limited health care fraud reforms.¹²⁵ But although it created a Criminal Health Care Fraud Statute, 18 U.S.C. § 1347, which applied to both government and private payers, Congress only slightly expanded the Anti-Kickback Statute.¹²⁶ Specifically, in the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Congress extended the Anti-Kickback Statute’s protections beyond just Medicare and Medicaid to other federal health care programs such as TRICARE.¹²⁷ Congress based this limited expansion on the idea that private health plans did not need the protections of the Anti-Kickback Statute because those plans were primarily managed care plans, in contrast to government plans, which Congress perceived to be fee-for-service plans.¹²⁸

These terms require brief explanations. Fee-for-service refers to a “method in which doctors and other health care providers are paid for *each* service performed.”¹²⁹ This system is believed to encourage overutilization

¹¹⁹ Social Security Amendments of 1972, Pub. L. No. 92-603, § 242(b), § 242(c), 86 Stat. 1419 (1972).

¹²⁰ This history is set out in detail in Diké-Minor, *supra* note 6, at 114–42.

¹²¹ *Id.*

¹²² *See, e.g., id.* at 132, 136–37, 139–40, 149–50 (documenting support from law enforcement and private insurance providers).

¹²³ *Id.* at 126.

¹²⁴ *Id.*

¹²⁵ *Id.* at 144–47 (discussing the limited expansion of the Anti-Kickback Statute).

¹²⁶ *Id.*

¹²⁷ *Id.* at 145–46; Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996).

¹²⁸ Diké-Minor, *supra* note 6, at 146–47.

¹²⁹ *Glossary: Fee for Service*, HEALTHCARE.GOV, <https://www.healthcare.gov/glossary/fee-for-service/> (last visited Aug. 13, 2023) (emphasis added); Sharon L. Davies & Timothy Stoltzfus Jost,

because “[i]n a system where economic reward is predicated on how much one does, particularly if procedural services pay more than cognitive ones, it is human nature to do more since it pays more.”¹³⁰ Kickbacks would encourage self-referrals by thus exacerbating overutilization.

Managed care, on the other hand, is a term that “defies precise definition,”¹³¹ but broadly speaking, is:

[U]sed to denote health care financing arrangements that attempt to control health care costs by modifying the behavior of providers through clinical rules and financial incentives, that restrict enrolled consumers’ access to providers and care, and that attempt to integrate the delivery and financing of health care.¹³²

One example is capitation, where a provider gets a set fee for all services rendered to a patient, regardless of whether that patient receives the services or not.¹³³ In brief, because managed care plans seek to incentivize physicians to order only necessary care, Congress viewed them as less susceptible to kickback conduct.

2. *The Rationale Has Four Flaws*

Congress’s “private health plans are managed care plans” rationale does not justify excluding private insurance plans from the protections of the Anti-Kickback Statute for four reasons. First, government-funded plans (which, as noted, are protected by the Anti-Kickback Statute) include managed care plans. Second, private plans often feature a mix of managed care and fee-for-service systems. Third, managed care plans are susceptible to kickback conduct, albeit in different ways. Fourth, the Anti-Kickback Statute has safe harbors for managed care that exist to address the concerns that kickback laws could inhibit innovation, and the safe harbors can be modified or expanded.

i. Government Funded Programs Include Managed Care Plans

The two major government health care programs—Medicare and Medicaid—are primarily managed care programs, yet both are protected by the Anti-Kickback Statute.

Managed Care: Placebo or Wonder Drug for Health Care Fraud and Abuse?, 31 GA. L. REV. 373, 373 (1997).

¹³⁰ KONGSTVEDT, *supra* note 1, at 89.

¹³¹ Davies & Jost, *supra* note 129, at 379.

¹³² *Id.* Managed care encompasses various arrangements, including health maintenance organizations (HMOs) and preferred provider organizations (PPOs).

¹³³ *Id.* at 384.

Approximately seventy percent of Medicaid beneficiaries are enrolled in managed care programs,¹³⁴ making it the “dominant way in which states deliver services to Medicaid enrollees.”¹³⁵ Forty-one states use managed care models to deliver Medicaid services, and in twenty-eight of those states, more than seventy-five percent of Medicaid beneficiaries were in managed care organizations (MCOs).¹³⁶ Further, in 2021, payments to comprehensive risk-based MCOs accounted for the largest share—approximately fifty percent—of total Medicaid expenses, \$728 billion.¹³⁷ Many of these MCOs are operated by private for-profit firms.¹³⁸ Indeed, five publicly-traded private companies accounted for fifty percent of all Medicaid MCO enrollment.¹³⁹

Similarly, Medicare significantly features managed care plans. Medicare Part C, also referred to as Medicare Advantage, is the program through which beneficiaries can enroll in a private health plan and receive Medicare-covered Parts A, B, sometimes D benefits, and sometimes other supplemental benefits (e.g., vision coverage).¹⁴⁰ Enrollment in Medicare Part C plans has grown significantly such that a 2022 headline read: “Medicare Advantage Is Close to Becoming the Predominant Way That Medicare Beneficiaries Get Their Health Coverage and Care.”¹⁴¹ To illustrate that point, in 1999, approximately seven percent of all Medicare beneficiaries enrolled in Part C plans,¹⁴² but by 2022, that percentage had

¹³⁴ Elizabeth Hinton & Jada Raphael, *10 Things to Know About Medicaid Managed Care*, KFF (Mar. 01, 2023), <https://www.kff.org/medicaid/issue-brief/10-things-to-know-about-medicoid-managed-care/> (“72% of Medicaid beneficiaries enrolled in comprehensive managed care organizations (MCOs) nationally”); Robin Rudowitz, Alice Burns, Elizabeth Hinton & Maiss Mohamed, *10 Things to Know About Medicaid*, KFF (June 30, 2023), <https://www.kff.org/medicaid/issue-brief/10-things-to-know-about-medicoid/>.

¹³⁵ Hinton & Raphael, *supra* note 134.

¹³⁶ *Id.*

¹³⁷ *Id.* The precise percentage was fifty-two percent. Other spending was accounted for as follows: disproportionate share hospital (two percent), payments to Medicare (three percent), Fee-for-Service institutional long-term care (seven percent), Fee-for-Service home health and personal care (twelve percent), Fee-for-Service acute care (twenty percent), and other managed care (four percent). *Id.* at fig.4.

¹³⁸ *Id.* As of July 2020, fourteen “parent” firms accounted for sixty-two percent of enrollment. *Id.* (“Of the 14 parent firms, six are publicly traded, for-profit firms while the remaining eight are non-profit companies.”).

¹³⁹ *Id.* The five firms were UnitedHealth Group, Centene, Anthem (renamed Elevance), Molina, and Aetna/CVS.

¹⁴⁰ Medicare Part A generally covers hospital services, Part B generally covers professional services (e.g., outpatient doctor visits), and Part D covers prescriptions. *Talking About Medicare: Your Guide to Understanding the Program*, KFF (Jan. 15, 2012), <https://www.kff.org/report-section/medicare-at-a-glance/>.

¹⁴¹ Craig Palosky, *Medicare Advantage is Close to Becoming the Predominant Way that Medicare Beneficiaries Get Their Health Coverage and Care*, KFF (Aug. 25, 2022), <https://www.kff.org/medicare/press-release/medicare-advantage-is-close-to-becoming-the-predominant-way-that-medicare-beneficiaries-get-their-health-coverage-and-care/>. See also Fred Schulte, *Did Your Health Plan Rip Off Medicare?*, KFF HEALTH NEWS (Jan. 27, 2023), <https://khn.org/news/article/medicare-advantage-audits-investigation-cms-overpayment-recoup-billions/> (“[E]nrollment in the health plans has exploded over the past decade to over 30 million and is expected to grow further.”).

¹⁴² *An Overview of Medicare*, KFF, 2 fig.3 (Feb. 2019), <https://files.kff.org/attachment/issue-brief-an-overview-of-medicare>.

reached forty-eight percent, and is expected to reach sixty-one percent by 2031.¹⁴³ Of the 3,998 Medicare Advantage plans available nationwide in 2023, the *overwhelming* majority—ninety-eight percent—were managed care plans.¹⁴⁴ Private fee-for-service plans accounted for approximately one percent of Medicare Advantage Plans.¹⁴⁵

ii. Private Plans Feature Fee-For-Service Systems

Moreover, private health insurers in the United States do not exclusively use managed care models; like Medicare and Medicaid, they use a mix of models, including fee-for-service.¹⁴⁶ Some types of services, such as physician office visits, are predominantly under fee-for-service arrangements, regardless of private or public health insurance plans.¹⁴⁷

Indeed, notwithstanding efforts to shift away from fee-for-service towards risk-based alternatives, 2013 data showed that “fee-for-service not only remain[ed] the dominant payment method but ha[d] continued to grow, with nearly 95 percent of all physician office visits in 2013 reimbursed in this fashion.”¹⁴⁸ An American Medical Association (AMA) survey of physicians¹⁴⁹ reported that in 2018, eighty-seven percent of physicians responded that “their practice received payment through fee-for-service for care that they provided, making it by far the most commonly reported

¹⁴³ Juliette Cubanski & Tricia Neuman, *What to Know about Medicare Spending and Financing*, KFF (Jan. 19, 2023), <https://www.kff.org/medicare/issue-brief/what-to-know-about-medicare-spending-and-financing/>.

¹⁴⁴ Meredith Freed, Jeannie Fuglesten Biniek, Anthony Damico & Tricia Neuman, *Medicare Advantage 2023 Spotlight: First Look*, KFF (Nov. 10, 2022), <https://www.kff.org/medicare/issue-brief/medicare-advantage-2023-spotlight-first-look/>. Of the ninety-eight percent, fifty-eight percent were HMOs and forty percent were PPOs, both of which are different forms of managed care. *Id.*

¹⁴⁵ *Id.*

¹⁴⁶ The Professional Society for Health Economics and Outcomes Research (ISPOR), *US Healthcare System Overview-Background*, ISPOR, <https://www.ispor.org/heor-resources/more-heor-resources/us-healthcare-system-overview/us-healthcare-system-overview-background-page-1> (last visited Aug. 15, 2023) (“Private insurers pay hospitals based on DRGs, case rates, per diems, fee-for-service, and/or discounted fee-for-service schemes.”); Davies & Jost, *supra* note 129, at 390 (“[F]ee-for-service is alive and well under managed care. There are few ‘pure’ managed care arrangements in which all providers are paid on a pre-paid or fixed cost basis.”); *Waste, Fraud and Abuse in the Medicare Program: Joint Hearing Before the Subcomm. on Health and Environment and the Subcomm. on Oversight and Investigations of the H. Comm. on Commerce*, 104th Cong. 31, 35 (1995) (testimony and prepared statement of Kirk J. Nahra, General Counsel, National Health Care Anti-Fraud Association) (“[F]ew plans represent ‘pure’ managed care. In almost all managed-care models, many services and patient options are not covered by fixed prepayments but rather are billed and paid on a fee-for-service basis.”).

¹⁴⁷ APOORVA RAMA, PAYMENT AND DELIVERY IN 2018: PARTICIPATION IN MEDICAL HOMES AND ACCOUNTABLE CARE ORGANIZATIONS ON THE RISE WHILE FEE-FOR-SERVICE REVENUE REMAINS STABLE 5, AM. MED. ASS’N, (Sept. 2019), <https://www.ama-assn.org/system/files/2019-09/prp-care-delivery-payment-models-2018.pdf> (“[I]n 2013, 94.7 percent of all physician office visits were covered under FFS arrangements. These results suggest that payments/reimbursements received by the practice are primarily through FFS.”); Davies & Jost, *supra* note 129, at 390 (“Most plans include at least some carve-outs or specialist contracts where fee-for-service remains, and many plans operate solely on a discounted fee-for-service basis.”).

¹⁴⁸ Samuel H. Zuvekas & Joel W. Cohen, *Fee-for-Service, While Much Maligned, Remains the Dominant Payment Method for Physician Visits*, 35 HEALTH AFFS., 411, 411 (2016).

¹⁴⁹ *Id.* at 412 (describing the AMA Physician Practice Benchmark Surveys).

payment method.”¹⁵⁰ The AMA report also noted that fee-for-service was the “principal component of [physician] practice revenue over the 2012 to 2018 period.”¹⁵¹ That growth is likely attributable to the fact that, as discussed in the next section, although managed care systems with capitated payments may restrain costs, they also raise “serious concerns . . . about physician incentives for providing high-quality care and willingness to accept financial risk.”¹⁵²

In summary, because private health insurers do not operate exclusively under a managed care model, “all of the traditional forms of fraud and abuse which thrive within fee-for-service medicine continue in some forms of managed care.”¹⁵³ This fact further undermines the private health plans are managed care plans justification for excluding private health plans from the Anti-Kickback Statute’s protections.

iii. Managed Care Plans Are Susceptible to Kickbacks

Private plans are not only susceptible to traditional kickback fraud through the fee-for-service carve-outs, but their managed care components are also susceptible to fraud from kickbacks, albeit to a lesser degree.¹⁵⁴ Fee-for-service and managed care systems set up incentives for kickback payments, even if they do so in different ways.¹⁵⁵ The fee-for-service system incentivizes kickback payments because it pays providers based on services, thereby encouraging providers to increase volume in order to increase fees.¹⁵⁶ Stated differently, it creates “temptations to ‘overutilize,’” thus “leading some providers to pay bribes or kickbacks to each other in order to generate referrals of patients to themselves, and leading other providers to ‘self-refer’ patients to entities with which they have investment or compensation arrangements.”¹⁵⁷

In contrast, managed care programs use capitation payments, which can discourage the acceptance of kickbacks that could lead to overutilization because a provider knows he or she will only receive a fixed amount for that patient and would want to avoid spending those funds on unnecessary care.¹⁵⁸ The same does not, however, apply to the desire to recruit healthy

¹⁵⁰ RAMA, *supra* note 147, at 5. *See also id.* at 6 (“[S]ince 2014, approximately one-third of physicians reported that all their revenue came from FFS and another 45 percent that more than half (but not all) came from FFS.”).

¹⁵¹ *Id.* at 8.

¹⁵² Zuvekas & Cohen, *supra* note 148, at 411.

¹⁵³ Davies & Jost, *supra* note 129, at 390.

¹⁵⁴ *See also* James F. Blumstein, *The Fraud and Abuse Statute is an Evolving Health Care Marketplace: Life in the Health Care Speakeasy*, 22 AM. J.L. & MED. 205, 205 (1996) (“The antikickback section has significantly less relevance to a capitated health care system in which the payment system itself inhibits overutilization and other costly practices.”) (citation omitted); Pamela H. Bucy, *Health Care Reform and Fraud by Health Care Providers*, 38 VILL. L. REV. 1003, 1021, 1033–34 (1993).

¹⁵⁵ Bucy, *supra* note 154, at 1021.

¹⁵⁶ *Id.* at 1013–14.

¹⁵⁷ Davies & Jost, *supra* note 129, at 384 (discussing examples of fraud with fee-for-service).

¹⁵⁸ Bucy, *supra* note 154, at 1021, 1033–34. Kickbacks may be less prevalent, but they still exist.

patients or to avoid unhealthy patients.¹⁵⁹ This is because managed care programs are incentivized to increase the number of overall healthy patients in order to increase the total capitated payments and savings.¹⁶⁰ The kickback would be paid “to encourage or reward referrals of healthy patients who require few health care services but for whom the provider is paid the same amount as it is paid for ill patients”¹⁶¹ and similarly to discourage the referral of high-risk patients.¹⁶² Further, the same does not apply to referring patients to specialists who are unlikely to be subject to a capitation system given that many patients are unlikely to need to see a specialist.¹⁶³

iv. Concerns with the Anti-Kickback Statute’s Interaction with Managed Care Can Be Addressed Through a Safe Harbor

Recognizing that Medicare and Medicaid offer managed care plans and seeking to allow for potentially beneficial arrangements, Congress instructed the Department of Health and Human Services to create safe harbors for MCOs.¹⁶⁴ The Department subsequently created two.¹⁶⁵ The first¹⁶⁶ “protects various financial arrangements between managed care entities that receive a fixed or capitated amount from the Federal health care programs and individuals and entities with whom the managed care entity contracts for the provision of health care items or services.”¹⁶⁷ The second,¹⁶⁸ “protects contractual relationships between managed care entities and their contractors and subcontractors” in certain circumstances.¹⁶⁹ These safe

¹⁵⁹ *Id.*

¹⁶⁰ Davies & Jost, *supra* note 129, at 387–88.

¹⁶¹ Bucy, *supra* note 154, at 1033; Davies & Jost, *supra* note 129, at 384 (“Providers paid on a per-patient capitated basis face incentives to maximize their consumer populations (and in particular their population of healthy consumers) while minimizing the items and services that they provide consumers.” This discussion is focused on capitation at the provider payment level. Capitation can occur at multiple levels. For instance, an employer may pay a health maintenance organization (HMO) a fixed amount for every employee or employee family group, and the HMO may then pay the providers capitated payments or discounted fees for service. Blumstein, *supra* note 154, at 210–11. Or a payee such as Medicare, could pay Part C insurance plans capitated payments, and those plans may pay providers in various forms. One commentator noted that as of 1994, “the great majority of managed care physicians receive FFS payments.” *Id.* at 211 (internal citation omitted).

¹⁶² Davies & Jost, *supra* note 129, at 388. *See also id.* at 388–89 (discussing a case example).

¹⁶³ *See* KONGSTVEDT, *supra* note 1, at 425 (listing an “indicator[] of health care fraud in a managed care setting, regardless of plan type” as “[h]igh levels of referrals of patients to specialist (may be a sign of a kickback arrangement)”).

¹⁶⁴ Federal Health Care Programs: Fraud and Abuse; Statutory Exception to the Anti-Kickback Statute for Shared Risk Arrangements, 64 Fed. Reg. 63504, 63507 (Nov. 19, 1999) (to be codified at 42 C.F.R. pt. 1001).

¹⁶⁵ 42 C.F.R. § 1001.952(t), (u) (2022).

¹⁶⁶ 42 C.F.R. § 1001.952(t) (2022).

¹⁶⁷ Federal Health Care Programs: Fraud and Abuse; Statutory Exception to the Anti-Kickback Statute for Shared Risk Arrangements, 64 Fed. Reg. 63504, 63,505 (Nov. 19, 1999) (to be codified at 42 C.F.R. pt. 1001).

¹⁶⁸ 42 C.F.R. § 1001.952(u) (2022).

¹⁶⁹ Federal Health Care Programs: Fraud and Abuse; Statutory Exception to the Anti-Kickback Statute for Shared Risk Arrangements, 64 Fed. Reg. 63504, 63505 (Nov. 19, 1999) (to be codified at 42 C.F.R. pt. 1001).

harbors have a number of requirements, many similar to those of other safe harbors, including that the parties must have an agreement that is written and signed by the parties, specifies the items and services covered by the agreement, and is set for a specific period of time.¹⁷⁰ Accordingly, Congress could address additional concerns with respect to private insurance plans and managed care through a safe harbor.¹⁷¹

C. *Excluding Private Payers Hampers Prosecutors' Ability to Address Health Care Fraud*

The limited reach of the Anti-Kickback Statute hampers prosecutors' ability to address health care fraud. First, it can result in fraud-shifting. Second, it can negatively impact prosecutors' ability to prove intent and discourage prosecutors from bringing cases based on concerns around jury appeal. Third, it requires prosecutors to charge cases in ways that do not align with the conduct.

1. *Excluding Private Health Insurance Plans May Cause Fraud-Shifting*

The failure to include private payers under the protections of the Anti-Kickback Statute likely results in “fraud shifting.”¹⁷² Indeed, in light of the Anti-Kickback Statute's application to just government health insurance plans, “[s]ome kickback schemes start by avoiding Medicare and Medicaid business until after referral patterns are established.”¹⁷³ The NHCAA has warned that “any legislative effort[] that focuses solely on increasing enforcement activities and the legal penalties related to fraud against government health insurance programs—without addressing the private sector side of the fraud equation—is likely to result in a ‘fraud-shifting’ analogous to the familiar cost-shifting phenomenon.”¹⁷⁴ The GAO has echoed this concern, with one report noting that “efforts to combat the

¹⁷⁰ *Id.* at 63507.

¹⁷¹ This would require careful study, notice, and comment as has been the case with prior safe harbors. *See, e.g., supra* note 164 and accompanying text. Congress's authority to delegate to agencies the power to modify criminal statutes has been affirmed. *See United States v. Gundy*, 139 S. Ct. 2116, 2123 (2019) (plurality opinion) (holding that the Sex Offender Registration and Notification Act's (SORNA) provision authorizing the Attorney General to specify the applicability of SORNA's registration requirements to offenders convicted of sex offenses before SORNA's enactment did not violate the nondelegation doctrine); *Touby v. United States*, 500 U.S. 160, 167 (1991) (holding that Congress could delegate authority to the Attorney General to add or remove substances from the Controlled Substances Act as long as it provided sufficient guidance and restrictions to constrain the Attorney General's discretion); *United States v. Motamedi*, Nos. 20-10364, 20-10366, 20-10367, 2022 WL 101951, at *1 (9th Cir. Jan. 11, 2022) (rejecting a challenge to the HHS Secretary's authority to issue safe harbors under the non-delegation doctrine). However, Congress should continue to do so clearly, including by listing statutory safe harbors where possible. *See West Virginia v. EPA*, 142 S. Ct. 2587 (2022).

¹⁷² H.R. REP. NO. 104-747, at 2 (1996) (“Scarce enforcement resources are wasted when Federal enforcement efforts to protect Medicare and Medicaid only result in ‘fraud shifting’ to private payers.”).

¹⁷³ *Id.* at 8.

¹⁷⁴ *Id.* at 11.

problems by one insurer can be largely negated when fraudulent or abusive providers move their operations to other insurers.”¹⁷⁵ Recognizing this problem, in 2013 the Department of Health and Human Services’ Office of the Inspector General issued an advisory opinion explicitly denouncing agreements where healthcare professionals have either refused to accept or have “carve[d] out” federal payor recipients from otherwise “questionable financial agreements.”¹⁷⁶

Thus, excluding private health insurers from the Anti-Kickback Statute may actually increase fraud against them, and without the Anti-Kickback Statute, prosecutors have fewer tools to address that conduct.

2. *Excluding Private Health Insurance Plans Creates Unnecessary Intent Problems*

Excluding private payers from the Anti-Kickback Statute also unnecessarily complicates a prosecutor’s ability to prove intent in kickback cases. Take the following scenario. A sales representative for a brace company offers to pay a doctor a set fee for every referral that he or she makes for patients with private health insurance. The sales representative does so with the expectation that the doctor will refer all patients to his or her company for braces—including those with government health insurance. Under the “one purpose” rule, which derives from case law, this conduct is technically covered by the Anti-Kickback Statute, because one purpose of the kickbacks was to induce referrals for services paid for by government payers.¹⁷⁷ A prosecutor might be able to prove that the goal of the arrangement was to incentivize the physician to make referrals for braces paid for by government health care programs, and thus is covered by the Anti-Kickback Statute. However, the prosecutor must consider whether that case would have any real jury appeal as it is perfectly legitimate for a jury (and judge) to ask why it is legal to take payments in one scenario and not the other. A Department of Justice official recognized a similar difficulty:

Our anti-kickback enforcement efforts have confronted significant obstacles because of the limited coverage of the current Medicare/Medicaid anti-kickback statute. Defense counsel routinely argue that the statute does not apply unless the majority or totality of a provider’s business is paid for by Medicare/Medicaid. For this reason, kickback prosecutions are vigorously defended and require extensive prosecutorial

¹⁷⁵ U.S. GOV’T ACCOUNTABILITY OFF., *supra* note 12, at 1–2. See also *Gaming the Health Care System: Trends in Health Care Fraud: Hearing Before the S. Spec. Comm. on Aging*, 104th Cong. 1 app. at 171 (1995) (investigative report of Sen. William S. Cohen explaining, “Often, even when law enforcement shuts down a fraudulent scheme, the same players resurface and continue their fraud in another part of the health care system.”).

¹⁷⁶ Dep’t. of Health & Hum. Servs., Off. of Inspector Gen., Advisory Opinion No. 13-03, at 4–5 (June 7, 2013).

¹⁷⁷ *United States v. Greber*, 760 F.2d 68, 69 (3d Cir. 1985).

resources. In addition, because of the limited coverage of the existing statute, many providers are not deterred by it¹⁷⁸

Faced with limited resources, a high case load, and the challenge of making technical distinctions between kickbacks for government and private covered services to a judge or jury, a prosecutor is unlikely to proceed with that case, regardless of how high the loss amounts are to government health care programs (and private payer programs).

3. *Excluding Private Health Insurance Plans Forces Prosecutors to Charge Cases in Ways that Do Not Fully Reflect the Conduct*

A prosecutor faced with a health care fraud scheme that involves kickbacks can only charge those payments that led to a billing by a government health insurance plan, causing the prosecutor to charge the case in ways that might not reflect the worst conduct. Take, for instance, a compounded cream fraud scheme in which a pharmacy pays multiple doctors to prescribe compounded creams for their patients and in which the doctors will be paid a percentage of whatever the pharmacy successfully bills for each prescription the doctors write. Doctor *C* sees primarily Medicare patients and because Medicare pays low amounts for the creams, would be paid a low kickback payment. Doctor *D*, on the other hand, has patients with very high reimbursing insurance, and accordingly would be paid a high kickback amount.¹⁷⁹ In charging a case against the pharmacy and its owners, a prosecutor would obviously want to use the larger, more egregious kickback payments since the payments incentivized the fraudulent prescriptions regardless of the patient's insurance plan. However, because the Anti-Kickback Statute is limited to government insurance plans, the prosecutor is forced to use the less egregious conduct as the charged count.

IV. EXISTING LAWS DO NOT ADEQUATELY ADDRESS THE PROBLEM

Several federal laws—specifically EKRA,¹⁸⁰ the Criminal Health Care Fraud Statute,¹⁸¹ the Travel Act,¹⁸² and the Honest Services Fraud Statute¹⁸³—arguably fill the gap left by the Anti-Kickback Statute. This section explains why they do not.

¹⁷⁸ *Health Care Fraud and Abuse: Hearing Before the Subcomm. on Hum. Res. & Intergov. Rels., H. Comm. on Gov't Reform & Oversight*, 104th Cong. 134 (1995) (statement of Gerald M. Stern, Special Counsel, Health Care Fraud, Department of Justice).

¹⁷⁹ For an illustration of how payment amounts for the same drugs can markedly vary by payer, see Indictment ¶ 85, *United States v. Adams*, No. 6:19-cr-00219 (N.D. Ala. Apr 24, 2019).

¹⁸⁰ 18 U.S.C. § 220.

¹⁸¹ 18 U.S.C. § 1347.

¹⁸² 18 U.S.C. § 1952.

¹⁸³ 18 U.S.C. § 1346.

A. *Eliminating Kickbacks in Recovery Act*

EKRA does not resolve the issues with the Anti-Kickback Statute given the limited number of opioid-related items and services to which it applies—recovery homes, clinical treatment facilities, and laboratories.

Recall Doctors *A* and *B*. Both were paid to order compounded creams for patients. However, Doctor *A* was paid to do so for patients with government-funded health insurance and Doctor *B* was paid to do so only for patients with private insurance. Notwithstanding their almost identical conduct, they would be treated differently under the existing federal criminal anti-kickback laws.

Doctor *A* (and Sales Representative *A* who did the offering or paying) could be prosecuted under the Anti-Kickback Statute because the referrals in question would have been paid for by a government-funded health program and fall under the very broad umbrella of “any” referrals. They could not, however, be prosecuted under EKRA because, even though EKRA applies to both government-funded and private health insurance programs, it applies only to referrals to a recovery home, clinical treatment facility, or laboratory, and compounded creams do not fall under any of these categories.¹⁸⁴

In contrast, Doctor *B* (and Sales Representative *B*) could not be prosecuted under either the Anti-Kickback Statute or EKRA. They could not be prosecuted under the Anti-Kickback Statute because the referrals in question would not be paid for by a government-funded program. And, although EKRA would cover referrals paid for by private health insurance, they could not be prosecuted under EKRA because the referrals do not qualify as a referral to a recovery home, clinical treatment facility, or laboratory.¹⁸⁵

If the hypothetical were changed slightly, making the items or services in question referrals to a “recovery home” for substance abuse-related treatment, things would change. Doctor *A* (and Sales Representative *A*) could be prosecuted under the Anti-Kickback Statute, because it applies to “any” referral, and could also be prosecuted under EKRA, because “recovery homes” are a qualifying referral and because EKRA applies to any health care benefit program, whether government-funded or not.¹⁸⁶ Doctor *B* (and Sales Representative *B*) could be prosecuted only under EKRA because Doctor *B*’s practice does not involve government-funded health insurance.

If the hypothetical were changed again, making the items or services in question referrals to a blood testing “laboratory,” things would change yet again. Indeed, in this scenario, because EKRA adopts a general definition of

¹⁸⁴ 18 U.S.C. § 220(a)(1), (e).

¹⁸⁵ *Id.*

¹⁸⁶ 18 U.S.C. § 220(e)(3); 18 U.S.C. § 24(b).

laboratory that is not limited to only laboratory testing for opioid treatment,¹⁸⁷ both statutes could apply *even if* the laboratory testing was not related to opioid treatment or addiction.¹⁸⁸ Doctor *A* (and Sales Representative *A*) could be prosecuted under the Anti-Kickback Statute because the referrals would be paid for by a government-funded health insurance program and because referrals to a laboratory qualify as “any” referral.¹⁸⁹ Doctor *B* (and Sales Representative *B*), however, could not be prosecuted under the Anti-Kickback Statute because it only applies to referrals paid for by government-funded programs.¹⁹⁰ They could, however, be prosecuted under EKRA because the referrals fall within the limited subset of referrals that EKRA covers, even though the referrals are not related to substance abuse treatment.¹⁹¹

If this seems unnecessarily confusing and complicated, that is because it is. A much simpler approach would be to include private payers in the protections that the Anti-Kickback Statute offers.

B. *The Criminal Health Care Fraud Statute*

It is also fair to ask why, the Criminal Health Care Fraud Statute, often referred to as Section 1347—which as noted covers fraud against both government and private payers and was passed as part of HIPAA—provides insufficient protection to private payers. Section 1347 does not provide sufficient protection against the almost relentless nature of health care fraud that calls for tools that can help deter fraudsters from engaging in that fraud in the first place.

As previously noted, health care fraud is rampant and is estimated to account for three to ten percent of health care expenses.¹⁹² As discussed, kickbacks incentivize fraud. Indeed, kickbacks are very often an integral aspect of health care fraud schemes.¹⁹³ Providers do not engage in health care fraud “just ’cos.” They do it for the money, either via increased reimbursements that come to them directly (e.g., if the provider runs an in-house urine testing lab), or for payments that come to them in the form of kickbacks.¹⁹⁴ For that reason, kickbacks are a regular feature in health care fraud prosecutions.¹⁹⁵ Indeed, kickbacks have been a feature of all except

¹⁸⁷ 18 U.S.C. § 220(e)(4).

¹⁸⁸ *Id.*; 42 U.S.C. § 1320a-7b(b) (applying to “any item or service” or “any good, facility, service, or item”).

¹⁸⁹ 42 U.S.C. § 1320a-7b(b).

¹⁹⁰ 42 U.S.C. § 1320a-7b(b), (f).

¹⁹¹ 18 U.S.C. § 220(e)(4).

¹⁹² *See supra* note 26 and accompanying text.

¹⁹³ *See infra* note 195 and accompanying text.

¹⁹⁴ *Id.*

¹⁹⁵ *See, e.g.*, U.S. GOV’T ACCOUNTABILITY OFF., GAO-16-216, HEALTH CARE FRAUD: INFORMATION ON MOST COMMON SCHEMES AND THE LIKELY EFFECT OF SMART CARDS 12–13 (2016) (Using cases from 2010, the report identified 1,679 fraud schemes in the 739 cases it reviewed).

one of the Special Fraud Alerts that the Office of Inspector General has issued.¹⁹⁶

Consequently, tools that help eliminate the incentives to engage in that fraud—i.e., tools that help deter fraud—are essential in the fight against health care fraud.¹⁹⁷ Anti-kickback laws help fight that fraud, not just by providing the path to prosecuting it, but also by sending a strong message to providers that it is illegal to base patient decisions on anything other than the patients' medical interests, and thereby deter that fraud.¹⁹⁸

It is worth observing that to legitimately ask why a kickback law for private payers is needed when a broader health care fraud law exists, one should pose the same question about government payers. When the question is asked of both government and private payers, it turns it into a broader challenge to the need for *any* anti-kickback laws when broader fraud laws exist. As just discussed, kickbacks can help eliminate the incentives to commit fraud, thereby deterring fraud. But further, kickbacks are harmful

Approximately 68% of the 739 cases included more than one scheme, and 20.6% of the 739 cases included a scheme involving the payment of kickbacks to participants in the scheme). Press Release, Dep't of Just., Off. Pub. Affs., Justice Department Recovers Over \$2.2 Billion from False Claims Act Cases in Fiscal Year 2020 (Jan. 14, 2021) (reporting that in 2020 one of the largest DOJ civil settlements was from Novartis Pharmaceuticals Corporation, which paid over \$591 million to resolve claims that it paid kickbacks to doctors to induce them to prescribe its drugs. "Novartis sales representatives, on the instruction of their managers, selected high-volume prescribers to serve as paid 'speakers' to induce the prescribers to write Novartis prescriptions.").

¹⁹⁶ Special Fraud Alerts are issued by OIG and provide general guidance to the health care industry on violations of Federal law (including various aspects of the anti-kickback statute). See Off. Inspector Gen., Special Fraud Alert: OIG Alerts Practitioners to Exercise Caution When Entering Into Arrangements With Purported Telemedicine Companies (July 20, 2022) ("One common element of these schemes is the way Telemedicine Companies have used kickbacks to aggressively recruit and reward Practitioners to further the fraud schemes."); Dep't Health & Hum. Servs., Off. Inspector Gen., Special Fraud Alert: Speaker Programs (Nov. 16, 2020); Dep't Health & Hum. Servs., Off. Inspector Gen., Special Fraud Alert: Laboratory Payments to Referring Physicians (June 25, 2014); Dep't Health & Hum. Servs., Off. Inspector Gen., Special Fraud Alert: Physician Liability for Certifications in the Provision of Medical Equipment and Supplies and Home Health Services (Jan. 1999); Dep't Health & Hum. Servs., Off. Inspector Gen., Publication of OIG Special Fraud Alerts: Home Health Fraud, and Fraud and Abuse in the Provision of Medical Supplies to Nursing Facilities (Aug. 10, 1995); Dep't Health & Hum. Servs., Off. Inspector Gen., Publication of OIG Special Fraud Alerts (Dec. 19, 1994) (pertaining to Joint Venture Relationships, Routine Waiver of Part B Co-payments/Deductibles, Hospital Incentives to Referring Physicians, Prescription Drug Marketing Practices, and Arrangements for the Provision of Clinical Lab Service). One alert did not explicitly address the Anti-Kickback Statute. Dep't Health & Hum. Servs., Off. Inspector Gen., Updated Special Fraud Alert: Telemarketing by Durable Medical Equipment Suppliers (Jan. 2010) (updating alert originally published in March 2003). All special alerts are available at <https://oig.hhs.gov/compliance/alerts/>.

¹⁹⁷ KONGSTVEDT, *supra* note 1, at 423 (noting the difficulty in detecting fraud and that "[t]hose seeking to commit health care fraud have cited it as an easy way to get huge amounts of money with little risk of detection, prosecution, or punishment.") (citation omitted).

¹⁹⁸ Recognizing that some district judges give light sentences to health care fraud defendants, courts of appeals have emphasized that general deterrence is a primary objective of sentencing in health care fraud cases. See, e.g., *United States v. Howard*, 28 F.4th 180, 209 (11th Cir. 2022) ("[W]hen the government obtains a conviction' in a health care kickback prosecution, 'one of the primary objectives of the sentence is to send a message' to others who contemplate such schemes that their crime is a serious one 'that carries with it a correspondingly serious punishment.'" (quoting *United States v. Kuhlman*, 711 F.3d 1321, 1328 (11th Cir. 2013))).

beyond overutilization and fraud; as set out in Parts I and III, kickbacks also cause non-fraud harms to patients and the market.

C. Travel Act

Faced with incidents of kickback payments for services paid for by private payers and with the problems in charging kickback cases that ignore private kickbacks,¹⁹⁹ prosecutors have turned to the Travel Act, a sixty-year-old statute passed by Congress to address racketeering and corruption associated with organized crime, to address kickback conduct against private plans.²⁰⁰ The language of the Act is broad, and it among other things, punishes those who travel in interstate commerce or use the mail or facilities in interstate commerce with the intent to engage in unlawful activity, such as bribery where it violates state or federal law.²⁰¹ The Supreme Court has held that the Travel Act has broad application,²⁰² and accordingly, prosecutors have begun using it in health care fraud prosecutions involving kickbacks to private payers.²⁰³

As explained below, the Travel Act has at least four deficiencies as a “gap-filler”: (1) it relies on state bribery laws, which not all states have; (2) where bribery laws exist, they may not cover health care fraud; (3) where they exist, they may apply to only some of the individuals engaged in the kickback scheme; (4) it does not have the Anti-Kickback Statute’s safe harbors, thus potentially making conduct that Congress has carved out as beneficial under the Anti-Kickback Statute, prosecutable under the Travel

¹⁹⁹ See *supra* Part III.A.

²⁰⁰ 18 U.S.C. § 1952. Commentators have discussed the increased use of the Travel Act. See Maria Paniscotti, Comment, *Have We Travelled Too Far?: The Rise of the Travel Act in Health Care Corrupt Payment Cases*, 45 SETON HALL LEGIS. J. 495, 509 (2021) (describing the “Travel Act as the Federal Government’s Gap Filler.”); B. Scott McBride, *The Government’s Creative Use of the Travel Act in Healthcare Fraud Prosecutions*, MORGAN LEWIS (May 22, 2019), <https://www.morganlewis.com/blogs/healthlawscan/2019/05/the-governments-creative-use-of-the-travel-act-in-healthcare-fraud-prosecutions>; Susan Smith, *The Travel Act: Enforcing Prohibitions Against Referrals Through State Bribery Laws*, WOLTERS KLUWER: HEALTH LAW DAILY WRAP UP (June 14, 2018), [https://www.bakerdonelson.com/webfiles/Bios/Travel%20Act%20SP%20June%202018\(1\).pdf](https://www.bakerdonelson.com/webfiles/Bios/Travel%20Act%20SP%20June%202018(1).pdf); Jonathan S. Feld, Monica B. Wilkinson, Lea F. Courington & Alison L. Carruthers, *The Rise of the Travel Act*, BUS. CRIMES BULL. (Oct. 2017), <https://www.lawjournalnewsletters.com/2017/10/01/the-rise-of-the-travel-act/?slreturn=20230714103038>.

²⁰¹ 18 U.S.C. § 1952.

²⁰² *Perrin v. United States*, 444 U.S. 37, 41–49 (1979) (discussing the Travel Act’s legislative history and holding that the Travel Act encompassed conduct violating state commercial bribery statutes); Patrick D. Souter, *The Travel Act: Sixty-Year Old “New” Tool in Healthcare Fraud Enforcement*, ABA E-HEALTH (May 1, 2018), https://www.americanbar.org/groups/health_law/publications/aba_health_esource/2017-2018/may2018/travelact/.

²⁰³ Smith, *supra* note 200 (noting that there have been over fifty prosecutions in the District of New Jersey alone); Souter, *supra* note 202; Paniscotti, *supra* note 200, at 504–08; Fred Schulte, *Federal Investigation Into Spine Surgeries Uses Mob Laws to Target Health Care Fraud*, KFF HEALTH NEWS (Feb. 8, 2022), <https://khn.org/news/article/federal-investigation-spine-surgeries-racketeering-law-health-care-fraud/> (discussing investigation into a Texas consulting company for arranging spine surgery and other medical care for people injured in car crashes under the Travel Act).

Act; and (5) given these complications, Travel Act cases could lack jury (and prosecutor) appeal.²⁰⁴

As noted, first, the Travel Act covers only states with bribery statutes, which several states do not have.²⁰⁵

Second, the Travel Act depends on whether a state's bribery statute applies to health care kickbacks or just other forms of bribery.²⁰⁶ Given the multi-state nature of many health care fraud schemes, this can create complications in prosecution.²⁰⁷ For instance, can a physician in a state without a bribery statute be prosecuted for receiving a kickback from an entity in a state with a bribery statute or vice versa? Even if that question is answered in the affirmative, does the state statute apply to health care kickbacks? "Because the state statutes are unique and may not have been utilized by state authorities to penalize kickbacks in the health care context, there may be no state interpretive authority."²⁰⁸

Third, several states have modeled their commercial bribery statutes on the Model Penal Code, thus prohibiting the bribery/kickback conduct only where a fiduciary duty exists, and as relevant here, limit the existence of a fiduciary duty to "physicians."²⁰⁹ As Professor Elberg has explained:

The Anti-Kickback Statute applies broadly not only to physicians but to anyone involved in paying remuneration to induce referrals or recommendations for any items or services paid for by a federal health care program. . . . The Model Penal Code Commercial Bribery statute, on the other hand, applies only to physicians and their patients. . . . The state Commercial Bribery statutes not only recognize the existence of a fiduciary relationship between physicians and their patients, but its importance, making it a crime to cause a physician to violate the duty.²¹⁰

The Model Penal Code uses the term "physician" "only to refer to physicians—it does not hold others to the same level of fiduciary duties to patients."²¹¹ This means that where the Model Penal Code Commercial

²⁰⁴ Some challenges with utilizing the Travel Act are discussed in more detail in Smith, *supra* note 200, and Paniscotti, *supra* note 200, at 508–22.

²⁰⁵ Smith, *supra* note 200 (discussing this limitation and noting that "ten states currently have no commercial bribery or related statute").

²⁰⁶ *Id.*; Paniscotti, *supra* note 200, at 513 (discussing *United States v. Snyder*, No. 9:18-cr-80111 (S.D. Fla. June 7, 2019)).

²⁰⁷ *See, e.g.*, Indictment ¶ 3, *United States v. Adams*, No. 6:19-cr-00219 (N.D. Ala. Apr. 24, 2019); *see also infra* notes 236–238 and accompanying text.

²⁰⁸ Smith, *supra* note 200.

²⁰⁹ Elberg, *supra* note 51, at *31 ("Unlike the Anti-Kickback Statute, which focuses on the violation of the payor (i.e., the Medicare or Medicaid program), the state Commercial Bribery statutes focus is the doctor's violation of duties owed to the patients as a fiduciary.").

²¹⁰ *Id.* (alterations omitted) (citing MODEL PENAL CODE § 224.8(1)(c) (2021)); MODEL PENAL CODE § 224.8(3) ("A person commits a misdemeanor if he confers, or offers or agrees to confer, any benefit the acceptance of which would be criminal under this Section.").

²¹¹ Elberg, *supra* note 51, at *31 n.111.

Bribery statute undergirds the state bribery law, the Travel Act could only apply against *physicians* or persons who cause a *physician* to violate his or her duty. This could presumably sweep in third parties, such as sales representatives who would pay the kickback thereby causing the physician to violate his or her duty. It would not, however, apply to other medical providers such as physician assistants, nurse practitioners, and X-ray technicians, who could be equally susceptible to taking kickbacks.²¹²

Fourth, using the Travel Act as a gap-filler creates fairness concerns because it could preclude the defense from asserting safe harbors that would be available under the Anti-Kickback Statute.²¹³ Any exceptions would depend on the relevant state statute.

Finally, given the potential complexity and multiplicity of the underlying state statute(s), these cases could lack jury appeal. If a case involved conduct in four states and was charged accordingly, a prosecutor would have to make sure the jury understood the underlying applicable state statutes.

D. *The Honest Services Fraud Statute*

Professor Joan Krause has previously flagged the possibility that the Supreme Court's decision in *Skilling v. United States*²¹⁴ might result in the government using the Honest Services Fraud Statute, 18 U.S.C. § 1346, to prosecute kickback conduct.²¹⁵ The Honest Services Fraud Statute would not adequately fill the gap because: (1) the Supreme Court has strongly indicated that it would not apply to private individuals; and (2) the applicability of the Honest Services Fraud Statute depends on the finding of a fiduciary duty, which many actors in a health care fraud scheme would not have with patients or the payer.

To understand why Section 1346 is an inadequate gap-filler, it is necessary to understand the genesis and current standing of Section 1346.²¹⁶ Prior to 1987, courts generally held that the federal wire fraud and mail fraud statutes, Sections 1343 and 1341 respectively, prohibited "honest-services fraud," i.e., the deprivation of one's right to honest services.²¹⁷ However, in its 1987 *McNally v. United States* decision, the Supreme Court "rejected the entire concept of honest-services fraud and held that the mail fraud statute

²¹² See, e.g., Indictment ¶¶ 5–7, 10, 75–89, *United States v. Murphy*, No. 5:20-cr-00291 (N.D. Ala. Sept. 23, 2020) (discussing the applicability of the Model Penal Code to kickbacks).

²¹³ Smith, *supra* note 200.

²¹⁴ 561 U.S. 358 (2010).

²¹⁵ See Joan H. Krause, *Kickbacks, Honest Services, and Health Care Fraud After Skilling*, 21 ANNALS HEALTH L. 137 (2012) (analyzing the applicability of the Honest Services Fraud Statute to prosecute kickbacks).

²¹⁶ This overview is taken from *Percoco v. United States*, 143 S. Ct. 1130, 1135–37 (2023), the Court's most recent decision addressing Section 1346.

²¹⁷ *Id.* at 1135.

was ‘limited in scope to the protection of property rights.’”²¹⁸ Shortly after, however, Congress enacted Section 1346, which defined the term “scheme or artifice to defraud” (a term that appears in both the wire fraud and mail fraud statutes) to include “a scheme or artifice to deprive another of the intangible right of honest services.”²¹⁹ Years later, in *Skilling*, the Court rejected a challenge to the constitutionality of Section 1346, but concluded that the Statute “did not apply to all intangible rights of honest services whatever they might be,”²²⁰ but rather was limited in its reach to only the core of pre-*McNally* honest-services case law.²²¹ It described that core as including “offenders who, in violation of a fiduciary duty, participated in bribery or kickback schemes.”²²²

Subsequently, in 2023, in *Percoco v. United States*, a case involving a private individual, the district court instructed the jury that Percoco could be convicted of honest services fraud if he had a duty to provide honest services to the public during the time when he was not serving as a public official if “he dominated and controlled any governmental business and, second, [if] people working in the government actually relied on him because of a special relationship he had with the government.”²²³ Without providing the correct standard (and instead remanding for further proceedings), the Court held those instructions to be unconstitutionally vague.²²⁴ However, in doing so, it issued multiple statements that would put into serious question any attempts to use the honest-services fraud statute to address kickbacks paid to or received by providers. For instance, it stated, “[t]o be sure, the pre-*McNally* record on honest-services fraud is clearest when the Government seeks to prosecute *actual public officials*.”²²⁵ Similarly, it said, “*Skilling*’s teaching is clear. ‘[T]he intangible right of honest services’ must be defined with the clarity typical of criminal statutes and should not be held to reach an ill-defined category of circumstances simply because of a smattering of pre-*McNally* decisions.”²²⁶

The *Percoco* concurrence went further and would have held that Section 1346 was unconstitutionally vague.²²⁷ Indeed, it specifically questioned the scope of the fiduciary duty covered by Section 1346, stating “even 80 years after lower courts began experimenting with the honest-services-fraud

²¹⁸ *Id.* at 1136 (summarizing the holding of *McNally v. United States*, 483 U.S. 350, 358, 360 (1987)).

²¹⁹ *Id.*; 18 U.S.C. § 1346.

²²⁰ *Percoco*, 143 S. Ct. at 1136 (quoting *Skilling v. United States*, 561 U.S. 358, 404–05 (2010)) (internal quotation marks omitted).

²²¹ *Percoco*, 143 S. Ct. at 1137 (quotations omitted).

²²² *Skilling*, 561 U.S., at 407.

²²³ *Percoco*, 143 S. Ct. at 1135.

²²⁴ *Id.* at 1138. The Court did, however, indicate that private individuals can have a fiduciary duty to the public if the person is an agent or is delegated authority by the government. *Id.* at 1137–38.

²²⁵ *Id.* at 1137 (emphasis added).

²²⁶ *Id.* at 1137.

²²⁷ *Id.* at 1141–42 (Gorsuch, J., concurring).

theory, no one can say what sort of fiduciary relationship is enough to sustain a federal felony conviction and decades in federal prison.”²²⁸ It noted that the majority’s decision did not “explain[] what kinds of fiduciary relationships are sufficient to trigger a duty of honest services in the first place,” asking “[d]oes it also apply to private individuals who contract with the public? Or does it apply to everyone who owes some sort of fiduciary responsibility to others, including (say) a corporate officer?”²²⁹

Given the majority’s and concurrence’s statements in *Percoco* indicating that Section 1346 does not even apply to private parties engaged in entirely private business, it would be very risky (and unwise) for any prosecutor to use a Section 1346 honest services fraud theory to attempt to address kickback conduct against private plans. Indeed, although noting that prosecutors might seek to pursue kickback cases based on an honest services fraud theory,²³⁰ Professor Krause also recognized that establishing a fiduciary duty in this context is a complicated affair.²³¹

Further, even if Section 1346 could be interpreted as applying to private actors with duties to private individuals, relying on Section 1346 to prosecute kickback conduct impacting private payers would exempt many of the relevant parties from prosecution. It is true that some courts have found that a fiduciary relationship exists between physician and patient for purposes of Section 1346.²³² Several, however, have rejected the argument that a fiduciary relationship exists in other contexts, such as that between a physician and a payer,²³³ and are therefore unlikely to find a fiduciary

²²⁸ *Id.* at 1141.

²²⁹ *Id.* (quotations and citations omitted).

²³⁰ Joan H. Krause, *United States v. Nayak: The Application of Honest Services Mail and Wire Fraud to the Health Care Industry (Part I)*, BILL OF HEALTH: PETRIE FLOM CTR., HARV. L. SCH. (Nov. 21, 2014), <https://blog.petrieflom.law.harvard.edu/2014/11/21/united-states-v-nayak-the-application-of-honest-services-mail-and-wire-fraud-to-the-health-care-industry-part-i/> [hereinafter Krause Part I] (“*Nayak* signals an interest on the part of federal prosecutors in applying the post-*Skilling* honest services theory to bribes and kickback schemes in the health care industry.”).

²³¹ Joan H. Krause, *United States v. Nayak: The Application of Honest Services Mail and Wire Fraud to the Health Care Industry (Part II)*, BILL OF HEALTH: PETRIE FLOM CTR., HARV. L. SCH. (Nov. 24, 2014), <https://blog.petrieflom.law.harvard.edu/2014/11/24/united-states-v-nayak-the-application-of-honest-services-mail-and-wire-fraud-to-the-health-care-industry-part-ii/> [hereinafter Krause Part II] (“While the physician-patient relationship is commonly described as a fiduciary one, the characterization is far more complex than may first appear. The disparities in medical knowledge, as well as the inability of patients to access many services (such as prescription drugs) without physician involvement, give physicians a great deal of power over their patients—a characteristic fiduciary responsibility. Yet the relationship lacks other fiduciary hallmarks; the physician, for example, lacks the fiduciary’s traditional control over the beneficiary-patient’s money.”).

²³² See *United States v. Neufeld*, 908 F. Supp. 491, 500 (S.D. Ohio 1995); *United States v. Nayak*, 769 F.3d 978, 979 & n.1 (7th Cir. 2014) (noting that the district court found a fiduciary duty between the doctor and patient); *id.* at 981 (stating that *Nayak*’s “bribe-and-kickback scheme to drum up business for his surgery centers . . . appears to fall squarely within the scope of § 1346 as the Court construed it in *Skilling*.”); Krause Part II, *supra* note 231 (discussing *Nayak*’s discussion of fiduciary duties in health care context in more detail). See also Elberg, *supra* note 51, at *23 (reviewing non-honest-services-fraud cases and noting that “[d]ozens of courts have found a fiduciary relationship requiring physicians to disclose material information concerning a patient’s treatment.”) (citation omitted).

²³³ See *Neufeld*, 908 F. Supp. at 500; Krause Part II, *supra* note 232.

relationship to exist between payers or patients and third parties. The reluctance (and difficulty) in finding additional fiduciary relationships along with the language of *Percoco*, means that third parties such as company owners (e.g., of durable medical equipment) and sales representatives—parties that are repeat players in kickback schemes—would be exempted from prosecution. As illustrated by the cases, third parties such as sales representatives are often integral parts of kickback schemes,²³⁴ and a gap-filler that exempts them from prosecution would be incomplete and could have the problematic result of the recipient of the kickback (the physician) being prosecuted, but not the payer of the kickback (e.g., the sales representative).

V. A FEDERAL SOLUTION IS NEEDED

A. “Leave it to the States” is Not a Solution

Similarly, it is not an adequate solution to “leave it to the states” because some states do not have bribery laws and, moreover, health care fraud calls for federal involvement in light of the multi-state nature of this fraud, the resources required to prosecute it, and the skyrocketing national health care costs due, in part, to health care fraud.

First, as reflected in the discussion of the Travel Act, states take varying approaches to kickback laws. Thirty-five states “proscribe kickbacks and the like in the health care industry even if the goods or services are reimbursable only by private health insurance and involve no public money at all.”²³⁵ The others do not.

The second challenge is the nature of health care fraud. Many health care schemes are multi-state in nature, including actors in multiple states and shipments across state lines.²³⁶ And many involve multiple providers.

²³⁴ See, e.g., Press Release, Dep’t of Just., Off. Pub. Affs., Justice Department Charges Dozens for \$1.2 Billion in Health Care Fraud (July 20, 2022), <https://www.justice.gov/opa/pr/justice-department-charges-dozens-12-billion-health-care-fraud>; Press Release, Dep’t of Just., Off. Pub. Affs., 2020 National Health Care Fraud and Opioid Takedown (updated Sept. 30, 2020); Press Release, U.S. Att’y’s Office, N.D. Ala., Ten, Including Pharmacy Owners, Pharmacist, and Nurse Practitioner, Charged in Over \$200 Million Prescription Drug Fraud (May 6, 2019); Press Release, U.S. Att’y’s Off., D.N.J., President of New Jersey Clinical Laboratory and His Brother, a Senior Employee, Sentenced to Prison in \$100m+ Test Referral/Bribery Scheme (June 13, 2018); Katrice Bridges Copeland, *Liquid Gold*, 97 WASH. U. L. REV. 1451, 1474–77 (2020) (discussing the practice of patient brokering in drug rehabilitation services).

²³⁵ Scott B. McBride, Rachel Moseson Dikovics, Jarrett R. Schindler & Jessica M. Terry, *Updated: A Survey of Health Care Anti-Kickback Law at the State Level*, LOWENSTEIN SANDLER LLP (Dec. 13, 2021), <https://www.lowenstein.com/news-insights/publications/articles/updated-a-survey-of-healthcare-anti-kickback-law-at-the-state-level-mcbride-moseson-schindler-terry>.

²³⁶ See, e.g., Indictment ¶ 3, *United States v. Adams*, No. 6:19-cr-00219 (N.D. Ala. Apr. 24, 2019) (referencing that the underlying conduct took place across multiple states); Press Release, Dep’t of Just., Off. Pub. Affs., National Enforcement Action Results in 78 Individuals Charged for \$2.5B in Health Care Fraud (June 28, 2023) (discussing multi-state and international telemedicine scheme); Press Release, Dep’t of Just., Off. Pub. Affs., Thirteen Defendants Plead Guilty in \$126 Million Compounding

Indeed, one of the ways fraudsters attempt to avoid detection is by spreading their conduct across multiple insurers.²³⁷ As the NHCAA explained, they “spread false billings among many payers and insurers simultaneously, including public programs such as Medicare and Medicaid, thus increasing fraud proceeds while lessening their chances of being detected by any single insurer.”²³⁸ The multi-state and multi-payer nature of these schemes makes federal law more appropriate and effective.

Further, kickback and health care fraud cases require significant resources. These cases rely heavily on cooperation from insiders, reliance on documentation, and are made more difficult by the complexity of the case-specific subject matter, the health system, and the regulations and laws governing health care.²³⁹ Commentators have described prosecuting these cases as a “tedious” and “resource-intensive.”²⁴⁰ Investigating these cases requires resources that states, who already prosecute the vast majority of the nations’ crimes, may not have.²⁴¹

Finally, skyrocketing health care costs are a national concern, and fraud contributing to those costs and to the overall health of the system is of national interest. As noted, in 2021, national health expenditures in the United States reached \$4.3 trillion, accounting for 18.3% of its GDP.²⁴² Within that \$4.3 trillion, private health insurance was “the predominant source of health insurance coverage in the United States,”²⁴³ accounting for 29.9% of spending, with Medicare accounting for 22.3% and Medicaid or

Fraud Scheme (Oct. 27, 2021) (discussing “years-long, multi-state” compounding fraud scheme); H.R. REP. NO. 104-747, at 1, 9–10 (1996) (discussing multi-state cases).

²³⁷ *The Challenge of Health Care Fraud*, NAT’L HEALTH CARE ANTI-FRAUD ASS’N, <https://www.nhcaa.org/tools-insights/about-health-care-fraud/the-challenge-of-health-care-fraud/> (last visited Aug. 17, 2023).

²³⁸ *Id.*

²³⁹ Krause, *Following the Money*, *supra* note 31, at 345–51 (discussing the characteristics of the health care system that make it an attractive target for fraud); Pamela H. Bucy, *Fraud by Fright: White Collar Crime by Health Care Providers*, 67 N.C. L. REV. 855, 877 (1989) (“In addition to the unsuspecting naivete of victims, the fact that the crime is usually hidden in voluminous documentary materials also makes white collar crime difficult to investigate and prove.”).

²⁴⁰ U.S. DEP’T OF HEALTH & HUM. SERVS., OFF. OF THE INSPECTOR GEN., OCT. 1, 1982 - MAR. 31, 1983 SEMIANNUAL REP., at 155 (describing health care investigations as “tedious”); Krause, *Following the Money*, *supra* note 31, at 348 (explaining that “[t]he ability to hide wrongdoing within a complex set of documents or electronic communications is one of the key reasons investigating health care fraud is such a resource-intensive endeavor”). *See also* U.S. GOV’T ACCOUNTABILITY OFF., *supra* note 12, at 2, 4, 20–21.

²⁴¹ *See* Andrea M. Gardner & Kevin M. Scott, *Census of State and Local Law Enforcement Agencies, 2018 – Statistical Tables*, BUREAU JUST. STATS. (Oct. 19, 2022), <https://bjs.ojp.gov/sites/g/files/xyckuh236/files/media/document/cslea18st.pdf>.

²⁴² *NHE Fact Sheet*, CTRS. FOR MEDICARE & MEDICAID SERVS. (July 31, 2023), <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpend-data/nhe-fact-sheet> (providing national health expenditure data for the year 2021).

²⁴³ ROSSO, *supra* note 2 (pertaining to health care coverage and spending in 2021). The Congressional Research Service report puts health care expenditure at approximately \$4 trillion with private health insurance at 29.9% of the overall health care expenditures. *Id.*

Children’s Health Insurance Program (CHIP) 18.7%.²⁴⁴ Health care expenditures are only expected to grow; indeed, they have more than tripled since 1960²⁴⁵ and are expected to reach \$6.8 trillion—\$6,800,000,000,000—by the year 2030.²⁴⁶ If fraud is a significant part of that spending and if it contributes to higher costs, then it is in the federal interest to address fraud against all entities, public and private.

B. *Private Payers Cannot Address the Problem on Their Own*

For many of these same reasons, it would be unworkable to “leave it to the private payers” to address the problem. Because schemes often target multiple payers, addressing the full scope of the conduct would require coordination among multiple payers. Further, at least until discovery, one payer would only have enough information about the conduct against itself and would be unlikely to know of the fraud.²⁴⁷ This would matter for instance, in “upcoding” cases, where a physician is accused of billing for a higher billable office visit than the one provided.²⁴⁸ Without the full scope of the physician’s patient interactions with multiple patients (who would have different types of insurance), it would be difficult, if not impossible, to tell from the limited dataset whether the physician indeed upcoded.²⁴⁹ Similarly, the resources and time required could make pursuing these cases unattractive. With these concerns, along with concerns of losing network providers and the risk of legal liability, payers may not take any action at all,²⁵⁰ and when they do, it usually takes the form of “quietly terminat[ing] the physician to avoid adverse publicity and lawsuits claiming defamation.”²⁵¹

Finally, leaving it to private plans to pursue civil remedies raises fairness concerns related to subjecting individuals who defraud Medicaid and

²⁴⁴ *Id.* The remainder was accounted for by spending on other health insurance programs such as TRICARE, and out-of-pocket spending, which was 10.7% of total national health expenditures. *Id.* A 2019 report focused on employment sponsored insurance stated, “[c]ommercial health care spending, driven predominantly by health care prices, continues to climb at unsustainable rates.” HEALTH CARE COST INST., 2019 HEALTH CARE COST & UTILIZATION REPORT (Oct. 2021).

²⁴⁵ RYAN NUNN, JANA PARSONS & JAY SHAMBAUGH, A DOZEN FACTS ABOUT THE ECONOMICS OF THE U.S. HEALTH-CARE SYSTEM, HAMILTON PROJECT (2020), https://www.hamiltonproject.org/wp-content/uploads/2023/01/HealthCare_Facts_WEB_FINAL-1.pdf (“Sixty years ago, health care was 5 percent of the U.S. economy, . . . at 17.7 percent in 2018, it was more than three times that.”).

²⁴⁶ Press Release, Ctrs. For Medicare & Medicaid Servs, CMS Office of the Actuary Releases 2021-2030 Projections of National Health Expenditures (Mar. 28, 2022).

²⁴⁷ U.S. GOV’T ACCOUNTABILITY OFF., *supra* note 12, at 15.

²⁴⁸ U.S. DEP’T OF HEALTH & HUM. SERVS., OFF. INSPECTOR GEN., A ROADMAP FOR NEW PHYSICIANS: AVOIDING MEDICARE AND MEDICAID FRAUD AND ABUSE 10, https://oig.hhs.gov/documents/physicians-resources/947/roadmap_web_version.pdf.

²⁴⁹ *Id.*; U.S. GOV’T ACCOUNTABILITY OFF., *supra* note 12, at 15.

²⁵⁰ KONGSTVEDT *supra* note 1, at 75 (“It is not common to remove a physician from the network and must not be taken lightly for many reasons, including disruption to the network and the risk of legal liability.”).

²⁵¹ Davies & Jost, *supra* note 129, at 394; *see also* U.S. GOV’T ACCOUNTABILITY OFF., *supra* note 12, at 16, 21–22 (discussing the imposition of sanctions resulting from kickback schemes).

Medicare to criminal sanctions, while leaving only civil remedies for those who defraud private plans.

CONCLUSION

The Eliminating Kickbacks in Recovery Act was a good initial step in expanding the Anti-Kickback Statute's protections. It is time, however, for Congress to extend the Anti-Kickback Statute's protections to private payers. Kickbacks harm *both* government and private payers by incentivizing overutilization and fraud. They harm the beneficiaries of *both* payers by incentivizing care that results in patient harm. And kickbacks impede the competitiveness of the overall health market, which includes *both* payers, by giving an unfair advantage to participants who are willing to pay kickbacks, even if they offer lower-quality (or more expensive) products or services. Nor does the use of managed care by private payers resolve the need to extend the Statute's protections to them. Like government payers, private payers use a mix of fee-for-service and managed care programs, and contrary to what Congress appears to have understood, managed care programs are not immune from kickbacks. Indeed, the harm from limiting the Statute's protections to government payers goes beyond failing to address the above-described harms to private payers. The limited reach of the Statute can also actively hamper prosecutors' ability to address health care fraud. Other federal and state laws and private causes of action do not adequately address these harms, and accordingly, the Anti-Kickback Statute should be expanded to protect private payers as well.