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The Untold Story of the United States' Anti-Kickback Laws

Chinelo Diké-Minor*

Abstract

Anti-kickback laws—laws prohibiting payments to induce or reward referrals of health care—are a significant tool in the government's arsenal against health care fraud. However, although a majority of Americans have health coverage through private health insurance, the primary U.S. law addressing kickbacks, the Anti-Kickback Statute, protects only government health insurance plans (and not all of them at that). To date, the story of Congress's attempts to extend the protections of the Anti-Kickback Statute to private health insurance plans has not been told. This article tells that untold story, a story that centers on the multiple unsuccessful—but bipartisan—efforts during the Clinton health care reform era to expand the Anti-Kickback Statute's protections to private plans. Significantly, these efforts received support from law enforcement and the private insurance industry. It then tracks continued, albeit less in-depth, discussions of whether the Anti-Kickback Statute applied to private plans on the 2010 Affordable Care Act's ("ACA") and it discusses the passage, in 2018, of a second criminal anti-kickback law, the Eliminating Kickbacks in Recovery Act ("EKRA"), which with little to no discussion, took a different approach, and included both government and private plans in its protections, but only as it pertains to a limited subset of opioid-related activities. This article notes that in light of all the support from law enforcement and the private sector for expanding the Anti-Kickback Statute to private plans, EKRA's passage, may signify a willingness by Congress to reconsider the reach of the Anti-Kickback Statute. This article is the first in a two-part series on U.S. anti-kickback laws.

I. INTRODUCTION

Anti-kickback laws—laws prohibiting payments to induce or reward referrals of health care—are a significant tool in the government's arsenal against health care fraud.[1] However, although

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[1] *Fraud & Abuse Laws*, U.S. DEP'T OF HEALTH & HUM. SERVS., OFFICE OF INSPECTOR GENERAL, https://oig.hhs.gov/compliance/physician-education/fraud-abuse-laws/ (last visited Apr. 29, 2023). The primary federal criminal anti-kickback law is the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b. *Id.* Anti-kickback laws are narrower than fraud laws in that they seek to deter the conduct—payments to providers in exchange for the provider prescribing or referring a health care item or service—that often results in fraud (as well as patient harm). Broadly speaking, health care fraud laws cover conduct where a provider lies or makes misrepresentations to a health insurance plan about the services he or she provided in order get paid. *See, e.g.*, 18 U.S.C. § 1347 (created in 1996 as part of the Health Insurance Portability and Accountability Act, discussed *infra* at Part III.B).

almost 70% of Americans receive their healthcare through the private market,[2] the primary U.S. law addressing kickbacks, the Anti-Kickback Statute, protects only government health insurers like Medicare, Medicaid, and TRICARE.[3]

To date, the story of why Congress excluded private insurance plans from the protections of the Anti-Kickback Statute has not been told. Discussions of the Statute's legislative history have been limited to its initial passage and amendments elevating it to a felony and adjusting its intent requirements in the 1970s and 1980s. This article, one in a two-part series on U.S. anti-kickback laws,[4] discusses the less-known history, a history that includes multiple bipartisan—but unsuccessful—efforts during the Clinton health care reform era to

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[2] RYAN J. RUSSO, CONG. RSCH. SERV., IF10830, U.S. HEALTH CARE COVERAGE AND SPENDING 1 (2023). The 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 marked (*e.g.*, via the Affordable Care Act market exchanges).

[3] 42 U.S.C. § 1320a-7b(f). This differs from broader fraud laws which apply to both private and public health insurance plans. *See* 18 U.S.C. § 1347 (stating the primary federal criminal health care fraud law which protects both government and private health care plans). Medicare is a federal health coverage program for persons
age 65 and older and certain persons with disabilities. Medicaid is joint federal and state health coverage program for low-income Americans, who often have to meet additional criteria. TRICARE is the health coverage program for uniformed service members, retirees, and their families around the world. *See* RYAN J. RUSSO, CONG. RSCH. SERV., RL32237, HEALTH INSURANCE: A PRIMER 12–13 (2015) [hereinafter RUSSO, A PRIMER].

[4] *See generally* Chinelo Dike-Minor, *The Devil Made Me Do It: An Argument for Expanding the Anti-Kickback Statute to Cover Private Payers*, 56 CONN. L. REV. __ (forthcoming Dec. 2023) (arguing that the Anti-Kickback Statute should be expanded to include private health insurance programs and that the failure to do so has negative consequences in the fight against health care fraud).

expand the Anti-Kickback Statute's protections to private payers.[5] Significantly, these efforts received support from law enforcement and the private insurance industry.[6] Ultimately, however, they failed for two reasons. First, although there was bipartisan support for the kickback (and broader fraud) reforms, there was not bipartisan support for the broader health care reforms.[7] 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.[8] Second, as time went on, Congress concluded that private health plans did not need the protections of the Anti-Kickback Statute because those plans were primarily managed care plans.[9]

This article further tracks continued, albeit less in-depth, discussions of whether the Anti-Kickback Statute applied to private plans on the 2010 Affordable Care Act's ("ACA") private exchanges given that those plans received government funding, and the federal government's conclusion, without real explanation, that it does not. Finally, it discusses the passage, in 2018, of a second criminal anti-kickback law, the Eliminating Kickbacks in Recovery Act ("EKRA"), which took a different approach by including both government and private plans in its protections but limiting its protections to a limited subset of opioid-related activities.

As with the best (or worst) stories, this untold story of U.S. anti-kickback laws has an unsatisfactory ending. It ends with the present-day patchwork of incoherent anti-kickback laws—with laws protecting different types of insurance plans and different types of services[10]—perhaps a fitting match to the present-day patchwork that is the U.S.

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[5] *See infra* Part III.
[6] *See id*.
[7] *See generally* HAYNES JOHNSON & DAVID S. BRODER, THE SYSTEM: THE AMERICAN WAY OF POLITICS AT THE BREAKING POINT (1997).
[8] *See infra* note 82.
[9] In the second part in this series, I argue that conclusion was incorrect. *See id.*
[10] This incoherence and the challenges posed by these laws are discussed in the second part to this two-part series. *See id.*

healthcare system.[11] However, in light of all the support from law enforcement and the private sector for expanding the Anti-Kickback Statute to private payers, EKRA's passage, may signify a willingness by Congress to reconsider the reach of the Anti-Kickback Statute.

II. ENACTMENT AND INITIAL AMENDMENTS

Some of the history of the enactment and evolution of the Anti-Kickback Statute has been told, but without discussion of the attempts to expand it to cover private payers.[12] However, as with anything history-related, one must start at the beginning. The beginning here is 1965 when Medicare and Medicaid were created.[13]

A. 1965: Medicare and Medicaid Created

Prior to 1965, the United States did not have large-scale government-funded health care. That changed in 1965 when under President Lyndon B. Johnson, the United States created Medicare and

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[11] The U.S. health care system consists of multiple models that mix public and private payment systems and providers. It includes models with that are privately paid with private providers (*e.g.*, employer-sponsored insurance), publicly paid with private providers (*e.g.*, Medicare and Medicaid), publicly paid with public providers (*e.g.*, the Veterans System), publicly subsidized (*e.g.*, community health centers and emergency care), and out-of-pocket costs (*e.g.*, the uninsured). *See, e.g.*, RUSSO, *supra* note 1; RUSSO, A PRIMER, *supra* note 3, at 9-13.

[12] *See, e.g.*, United States v. Shaw, 106 F. Supp. 2d 103, 110–14 (D. Mass. 2000); Richard P. Kusserow, *The Medicare & Medicaid Anti-Kickback Statute and the Safe Harbor Regulations – What's Next?*, 2 HEALTH MATRIX: J.L. & MED. 49, 49–53 (1992) (discussing history and several safe-harbor provisions); Douglas A. Blair, *The "Knowingly and Willfully" Continuum of The Anti-Kickback Statute's Scienter Requirement: Its Origins, Complexities, And Most Recent Judicial Developments*, 8 ANNALS HEALTH L. 1, 4, 9-12 (1999) (providing an in-depth discussion of cases addressing the Anti-Kickback Statute's scienter requirement).

[13] For a fascinating and easy-to-digest summary of the history leading up to the creation of Medicare and Medicaid, *see*, *The Everlasting Problem*, NAT'L PUB. RADIO, (Oct. 1, 2020), https://www.npr.org/2020/09/28/917747287/the-everlasting-problem.

Medicaid which, in broad terms, provided health insurance for the elderly and poor, respectively.[14]

At that point, there were no laws specifically addressing the payment of kickbacks in relation to health care services. The Social Security Act did, however, contain a misdemeanor provision addressing fraudulent misrepresentations to obtain Medicare or Medicaid payments or services.[15]

B. 1972: Anti-Kickback Statute Created

In 1972, Congress created the Anti-Kickback Statute by amending the Social Security Act.[16] As Medicare and Medicaid costs rose, so did claims of fraud against the programs and Congress sought to act by creating the Anti-Kickback Statute. Congress explained that it sought to improve Medicare and Medicaid by penalizing "certain practices which have long been regarded by professional organizations as unethical, as well as unlawful in some jurisdictions, and which

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[14] U.S. DEP'T OF HEALTH & HUM. SERVS., CTRS. FOR MEDICARE AND MEDICAID SERV., TRACING THE HISTORY OF CMS PROGRAMS: FROM PRESIDENT THEODORE ROOSEVELT TO PRESIDENT GEORGE W. BUSH 3–4, https://www.cms.gov/About-CMS/Agency-Information/History/Downloads/PresidentCMSMilestones.pdf. Prior to Medicare and Medicaid, Congress passed the Kerr-Mills Act, which in 1960 created "a new means-tested program known as Medical Assistance for the Aged that provided federal funds to states choosing to cover health care services for seniors with incomes above levels needed to qualify for public assistance, but nonetheless in need of assistance with medical expenses." *Putting the Program in Context*, MEDICAID & CHIP PAYMENT & ACCESS COMM'N, https://www.macpac.gov/putting-the-program-in-context/ (last visited Feb. 23, 2023).

[15] 42 U.S.C. § 408 (1970).

[16] Social Security Amendments of 1972, Pub. L. 92-603 § 242, 86 Stat. 1329, 1419-20 (amending Social Security, Medicare, and Medicaid in various other significant ways). *See Shaw*, 106 F. Supp. 2d at 110-14 (discussing legislative and regulatory history of the Anti-Kickback Statute).

contribute appreciably to the cost of the [M]edicare and [M]edicaid programs."[17]

The 1972 version of the Anti-Kickback Statute prohibited "solicit[ing], offer[ing], or receiv[ing] any — kickback or bribe" and was a strict liability misdemeanor, with a maximum imprisonment of a year and a maximum fine of $10,000.[18] The Medicare and Medicaid misdemeanor provisions were separately codified, but generally identical.[19]

With regard to Medicare, the Statute then provided in relevant part:

> (b) Whoever furnishes items or services to an individual for which payment is or may be made under this title and who solicits, offers, or receives any-
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> (1) kickback or bribe in connection with the furnishing of such items or services or the making or receipt of such payment, or
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> (2) rebate of any fee or charge for referring any such individual to another person for the furnishing of such items or services,
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> shall be guilty of a misdemeanor and upon conviction thereof shall be fined not more than $10,000 or imprisoned for not more than one year, or both.[20]

Faced with the increasingly high costs of these newly created—and controversial—public programs and increased allegations of fraud

[17] H.R. REP. NO. 92-231 (1972), *as reprinted in* 1972 U.S.C.C.A.N. 4989, 5093.

[18] § 242, 86 Stat. at 1419-20.

[19] *Id.* at § 242(b) (Medicare); *id.* at § 242(c) (Medicaid).

[20] 42 U.S.C. § 1395(n)(n) (1972). *See also* 42 U.S.C. § 1396(h) (1972) (Medicaid provision).

within those systems, Congress concentrated its efforts on protecting Medicare and Medicaid from fraud.[21] Indeed, at this point, the Statute did not protect other government-funded programs like TRICARE.[22] Further, Congress did not give any real consideration to creating an anti-kickback law that would extend its protections to private health insurance.

C. 1977: First Expansion of the Anti-Kickback Statute

In 1977, following congressional hearings and investigations that pointed to significant fraud and abuse in the Medicare and Medicaid systems,[23] Congress amended the Anti-Kickback Statute through the Medicare-Medicaid Antifraud and Abuse Amendments.[24] With this round of amendments, Congress increased the punishment for violating the Anti-Kickback Statute making it a felony, punishable by up to five years imprisonment, and increasing the maximum fine to $25,000.[25] It also broadened the reach of the statute to prohibit "any remuneration" which was solicited, received, offered or paid "directly or indirectly, overtly or covertly, in cash or in kind."[26]

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[21] Theodore N. McDowell, Comment, *The Medicare-Medicaid Anti-Fraud and Abuse Amendments: Their Impact on the Present Health Care System*, 36 EMORY L.J. 691, 718–20 (1987) (noting that "It was estimated that fraudulent practices were costing taxpayers over one billion dollars a year.").

[22] 42 U.S.C. § 1395(n)(n) (1972) (Medicare); 42 U.S.C. § 1396(h) (1972) (Medicaid).

[23] McDowell, *supra* note 21, at 718–20 (discussing hearings and investigations).

[24] Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142, § 4, 91 Stat. 1175, 1179-83 (1977).

[25] *Id.*

[26] *Id.* at §4(b); Congress "expressly intended to define the term 'any remuneration' broadly." Kusserow, *supra* note 12, at 50 n.5 (citing legislative sources). The statutory language was in part broadened following disagreement among the courts of the meaning of kickback and bribe. *Compare* United States v. Porter, 591 F.2d 1048, 1052-54 (5th Cir. 1979) (defining "kickback" as the "return to an earlier possessor of part of a sum received") *with* United States v. Hancock, 604 F.2d 999, 1000-02 (7th Cir. 1979) (adopting a broad reading of kickback).

Congress explained that the purpose of this amendment was to address the "disturbing degree [of] fraudulent and abusive practices associated with the provision of health services financed by the [M]edicare and [M]edicaid programs."[27] It listed multiple findings that supported felonizing this conduct explaining that payment of kickbacks was widespread in the health industry and "adversely impacts … all Americans" by misusing taxpayer funds, diverting scare program dollars from "those most in need, the nation's elderly and poor," and eroding the "financial stability of those state and local governments whose budgets are already overextended and who must commit an ever-increasing portion of their financial resources to fulfill the obligations of their medical assistance programs."[28] As in 1972, Congress's focus was on protecting these newly created government programs, and not private programs, from fraud.

D. 1980s: Anti-Kickback Statute Narrowed and Expanded

The 1980s saw several events that both narrowed and expanded the scope of the Anti-Kickback Statute.

In 1980, Congress narrowed the scope of the Anti-Kickback Statute when it amended it to clarify that a conviction required proof of "knowing and willful" conduct; this amendment sought to ensure that the Statute could not be applied to inadvertent conduct.[29]

In 1985, in one of the most significant Anti-Kickback Statute cases to date, *United States v. Greber*, the Third Circuit adopted the government's more expansive view of the application of the Anti-Kickback Statute.[30] In *Greber*, the Third Circuit held that the Anti-Kickback Statute applied to a payment arrangement as long as "one

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[27] H.R. REP. NO. 95-393, pt. 2, at 44 (1977), *as reprinted in* 1977 U.S.C.C.A.N. 3039, 3047.

[28] *Id.*; *see also* United States v. Shaw, 106 F. Supp. 2d 103, 110–11 (D. Mass. 2000).

[29] Omnibus Reconciliation Act of 1980, Pub. L. No. 96-499, §§ 1877(b)(1), 1877(b)(2), 1909(b), 94 Stat. 2599 2625 (codified at 42 U.S.C.§§ 1320a-7b(b) (1994)); *see also* Blair, *supra* note 12, at 4.

[30] United States v. Greber, 760 F.2d 68, 69 (3d Cir. 1985).

purpose of the payment was to induce future referrals.[31] It thus adopted the view that the inducement of referrals did not have to be the primary or only purpose of the payments; it just had to be *one* of the purposes of the arrangement.[32]

In 1987, Congress again narrowed and expanded the reach of the Anti-Kickback Statute through the Medicare and Medicaid Patient and Program Protection Act ("MMPPA").[33] It narrowed it by directing the U.S. Department of Health and Human Services Office of Inspector General ("HHS OIG") to promulgate safe harbors, *i.e.*, payment and business practices that, although they potentially implicate the Anti-Kickback Statute, would not be treated as offenses under the Statute.[34] It also expanded the Statute by giving HHS-OIG the administrative remedy of exclusion, *i.e.*, the ability to exclude providers from the Medicare and Medicaid programs for violations of the Statute.[35]

In addition, the MMPPA brought the Medicare and Medicaid anti-kickback provisions into the present-day Anti-Kickback Statute.[36] Section (b)(1) of the Anti-Kickback Statute addresses the payer's conduct (or would-be payer's conduct) and prohibits the solicitation or receipt of remuneration, while Section (b)(2) addresses the payee's conduct (or would-be payee's conduct) and prohibits the offering or payment of remuneration. The maximum term of imprisonment and fine remained as five years and $25,000 respectively.

As with the 1972 and 1977 amendments, the Anti-Kickback Statute continued to protect only the Medicare and Medicaid programs from kickbacks and Congress showed no interest in changing that.

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[31] *Id.*
[32] *See generally Greber*, 760 F.2d at 68; James P. Prenetta Jr., *United States v. Greber: A New Era in Medicare Fraud Enforcement?*, 3 J. CONTEMP. HEALTH L. & POL'Y 309 (1987) (discussing *Greber* and related cases).
[33] Medicare and Medicaid Patient and Program Protection Act of 1987 (MMPPPA), Pub. L. No. 100-93, § 4, 101 Stat. 688 (1987).
[34] *Id.*
[35] *Id.*
[36] Social Security Act § 1128B(b), 42 U.S.C. 1320a-7b(b).

III. THE UNTOLD STORY: EFFORTS TO EXPAND THE ANTI-KICKBACK STATUTE'S PROTECTIONS TO PRIVATE INSURANCE PROGRAMS

In the 1990s, however, things changed with Congress making multiple attempts—with strong bipartisan support—to expand the Anti-Kickback Statute's protections to other government health care programs (beyond Medicare and Medicaid) and to private health care programs.

A. 1993 to 1996: Multiple Failed Attempts to Expand the Anti-Kickback Statute to Protect Other Health Insurance Programs

Between 1993 and August 1996, there were several efforts to extend the Anti-Kickback Statute's protections.[37] These efforts appear to have been initially inspired by reports from the United States General Accounting Office ("GAO") emphasizing that both government and private health care programs are vulnerable to health care fraud, that health care costs in both private and public health care programs were skyrocketing, and the view that reducing fraud would help reduce those costs.[38]

1. H.W. Bush Efforts

The efforts to extend the coverage of the Anti-Kickback Statute to other public and private insurance plans can be traced at least to January 13, 1993, when a task force appointed by President George H.W. Bush released recommendations to combat health care fraud and abuse.[39] The Task Force recommended "extending to all public and

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[37] *See, e.g.*, COMM. ON GOV'T REFORM AND OVERSIGHT, HEALTH CARE FRAUD: ALL PUBLIC & PRIVATE PAYERS NEED FEDERAL CRIMINAL ANTI-FRAUD PROTECTIONS, H.R. REP. NO. 104-747 (1996) [hereinafter HEALTH CARE FRAUD] (discussing several proposals).

[38] *See infra* notes 41 to 43.

[39] COMM. ON GOV'T REFORM AND OVERSIGHT, HEALTH CARE FRAUD: ALL PUBLIC & PRIVATE PAYERS NEED FED. CRIMINAL ANTI-FRAUD PROTECTIONS, H.R. REP. NO. 104-747 (1996) (quoting Press Release,

private payers the current Medicare and Medicaid prohibition on kickbacks."[40]

This recommendation followed GAO reports highlighting fraud against both public and private health insurance programs. For instance, in a May 1992 report entitled *Health Insurance: Vulnerable Payers Lose Billions to Fraud and Abuse*, GAO reported that "[b]oth public health insurance programs and private health insurers are vulnerable to fraud and abuse," and identified the inapplicability of federal anti-kickback statutes to private payers as one of the "obstacles to detecting fraud and abuse."[41] In an August 1992 report, GAO detailed a scheme that resulted in an estimated loss of $1 billion in fraudulent schemes to both public and private insurers.[42] Subsequently, in a December 1992 report looking at high-risk areas for fraud, the GAO again reiterated that "[f]raud and abuse problems beset all health payers" and stated that its work had shown that "Medicare's problems with prosecution and financial recovery are similar to those facing private health insurers."[43]

HHS/OMB/DOJ Administration Announces Task Force Recommendations to Combat Health Care Fraud and Abuse (Jan. 13, 1993) and citing the press release as available in subcommittee files).

[40] *Id.* (listing additional recommendations made by this task force).

[41] U.S. GOV'T ACCOUNTABILITY OFF., GAO/HRD-92-69, REPORT TO THE CHAIRMAN, SUBCOMM. ON HUMAN RESOURCES AND GOVERNMENT OPERATIONS: HEALTH INSURANCE: VULNERABLE PAYERS LOSE BILLIONS TO FRAUD AND ABUSE 4 (1992).

[42] U.S. GOV'T ACCOUNTABILITY OFF., GAO/HRD-92-76, REPORT TO THE SUBCOMM. ON HEALTH: MEDICARE: ONE SCHEME ILLUSTRATES VULNERABILITIES TO FRAUD AND ABUSE (1992).

[43] U.S. GOV'T ACCOUNTABILITY OFF., GAO/HR-93-6, HIGH-RISK SERIES: MEDICARE CLAIMS 8 & 24 (1992). GAO continued to emphasize that both public and private payers were vulnerable to fraud. *See, e.g.*, GAO TESTIMONY BEFORE THE SUBCOMM. ON CRIME & CRIMINAL JUSTICE COMM. ON THE JUDICIARY, H.R., GAO/T–HRD–93–3, *Health Insurance: Legal and Resources Constraints Complicate Efforts to Curb Fraud and Abuse*, at 1 (Feb. 1993) (statement of Janet L. Shikles, Director of Health Financing and Policy Issues Human Resources Division).

The Bush Administration did not act on the Task Force's recommendation. That inaction is unsurprising, however, because President Bush handed over the presidency to President William J. Clinton on January 20, 1993, just seven days after the Task Force released its recommendations.

2. Clinton Efforts

Soon after taking office, and in keeping with his campaign themes,[44] President Clinton began pushing health care reform.[45] On September 22, 1993, he formally presented his health care plan to the United States in a speech to a joint session of Congress.[46] His multifaceted plan, the American Health Security Act of 1993 ("HSA"), called for a managed competition system that would require all United States citizens and legal immigrants to be covered by health insurance.[47] In presenting his plan, Clinton argued that his proposed reforms would reduce the costs of health care.[48]

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[44] *Health Care Reform Initiative*, NAT'L ARCHIVES: CLINTON DIGITAL LIBR., [hereinafter *Health Care Reform Initiative*] https://clinton.presidentiallibraries.us/health-reform-initiative (last visited Feb. 23, 2023).

[45] *See* JOHNSON ET AL., *supra* note 7. Then First Lady Hillary Rodham Clinton led these efforts and chaired the Administration's Task Force on National Health Care Reform. *See Health Care Reform Initiative*, *supra* note 44.

[46] William J. Clinton, U.S. President, Health Care Remarks, Address Before the Members of Cong. (Sept. 23, 1993), *in* H.R. DOC. NO. 103-137 (1993).

[47] *Clinton Unveils Health-Care Reform Proposals to Cong.; 'Managed Competition' Plan Would Overhaul System; Coverage to Be Extended to All Americans*, FACTS ON FILE WORLD NEWS DIGEST (Sept. 23, 1993); *see generally* Mark A. Hall, *Managed Competition and Integrated Health Care Delivery Systems*, 29 WAKE FOREST L. REV. 1 (1994) (providing a fuller discussion of managed competition).

[48] 139 CONG. REC. H6895 (daily ed. Sept. 23, 1993) (health care remarks by William J. Clinton, United States President, before the Members of Congress); FACTS ON FILE WORLD NEWS DIGEST, *supra* note 47 (summarizing HSA).

Notably, one of the ways in which President Clinton proposed to reduce costs was to reduce health care fraud by strengthening the fraud and abuse laws. Describing the healthcare system as having "too much fraud and too much greed," he emphasized the need to "crack down on fraud and abuse in the system" because "[it] drains billions of dollars a year."[49] His efforts on this front were influenced by Attorney General Janet Reno, who reportedly told him in 1993 "that any health care reform act would need a strong fraud component."[50] Consistent with that viewpoint, in late 1993, General Reno "named health care fraud the [DOJ's] number two initiative—behind violent crime."[51]

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[49] 139 CONG. REC. H6895 (daily ed. Sept. 23, 1993) (health care remarks by William J. Clinton, United States President, before the Members of Congress).

[50] Jennifer Steinhauer, *Justice Dept. Finds Success Chasing Health Care Fraud*, N.Y. TIMES, Jan. 23, 2001, at A19.

[51] U.S. DEPT' OF JUST., HEALTH CARE FRAUD REP. FISCAL YEAR 1994, at 2 (1995); *Dep't of Justice Oversight, Hearing Before the Comm. on the Judiciary, U.S. Senate*, 103d Congress, J-103-65, 7 (July 28, 1994) (statement of Att'y Gen. Janet Reno) ("In recognition of the severity of this crisis, I made health care fraud one of our top priorities."). In the next few years, the Reno Department of Justice significantly increased the resources dedicated to, and number of health care fraud cases investigated and prosecuted. *See* MICHAEL LOUCKS & CAROL LAM, PROSECUTING & DEFENDING HEALTH CARE FRAUD CASES, 2 (2d ed. 2010) ("[B]efore 1980, there were virtually no health care fraud prosecutions anywhere in the United States . . . . That changed in the 1990s, and in the first 15 years of the 21st century saw an increase in health care prosecutors."). Health care fraud had been a focus of the Department of Justice prior to 1994, but it had not been elevated to the number two priority. *See, e.g.*, *Dep't of Just. Authorization for Fiscal Year 1993 Before the Senate Comm. On the Judiciary*, 103d Cong. 8 (1992) (statement of Bill Barr, Att'y Gen.), https://www.justice.gov/sites/default/files/ag/legacy/2011/08/23/06-30-1992.pdf ("Another major focus in our fight against white collar crime is health care fraud.").

On November 20, 1993, H.R. 3600 and S.1757, President Clinton's health care bill was introduced in the House and Senate, respectively.[52] As part of its comprehensive health reform, the HSA proposed substantial additions and changes to fraud and abuse laws in the health context. The HSA had three primary fraud and abuse related goals.[53] It sought to "provide a more coherent framework for civil and criminal investigative and enforcement efforts," "broaden the civil and criminal sanctions available to fight health care fraud" and of particular significance to this article, "integrate 'private' third-party payers into the federal civil and criminal investigative and enforcement scheme."[54] One of the ways it sought to do this was by creating new health care fraud laws, including a criminal health care fraud provision that would address fraud against both private and public payers.[55] At that time, the

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[52] H.R. 3600, 103rd Cong. (1993); S. 1757, 103d Cong. (1993). The House bill was sponsored by Richard Gephardt, Democratic Congressman from Missouri. The Senate version was sponsored by George Mitchell, Democratic Senator from Maine.

[53] For an overview of the various fraud and abuse sections of the HSA, *see Health Care Fraud: Examining Federal, State, and Local Efforts to Combat Fraud and Abuse in the Health Care Industry and Related Provisions of the Proposed Health Security Act, Hearing Before the Committee on the Judiciary*, 103rd Cong. 120–25 (1994) (Mem. from Thomas W. Brunner & Kirk J. Nahra, counsel to NCHAA, The Anti-Fraud Implications of the Clinton Health Care Proposal) [hereinafter NCHAA General Counsel Mem. on HSA]; Barry D. Alexander, *Health Reform: False Claims Enforcement Under a New Regime*, 24 PUB. CONT. L. J. 103, 107–17 (1994). .

[54] NCHAA General Counsel Mem. on HSA, *supra* note 53.

[55] H.R. 3600, 103d Cong. § 5431 (1993). The HSA also proposed amending the forfeiture laws to allow for forfeitures of certain violations relating to health care fraud, *id.* § 5432, and proposed a felony statute that would prohibit making false statements in health care matters, giving bribes to influence health care officials' conduct, and engaging in theft or embezzlement in connection with health care plans, *id.* §§ 5433, 5434, 5437. In addition, it proposed to amend a civil injunction statute to allow the

federal government primarily relied on the general mail and wire fraud statutes,[56] to address health care fraud.

In addition, the HSA made several proposals to strengthen the criminal Anti-Kickback Statute, which were supported by DOJ.[57] Specifically, it sought to increase the maximum fine for a violation from $25,000 to $50,000; give courts the authority to assess "damages" against defendants of up to three times the total remuneration they offered, paid or solicited;[58] and modify the safe harbor provisions.[59] In addition, it proposed to explicitly incorporate *Greber*'s one-purpose rule into the statute.[60] Notably, and of particular interest to this article, the HSA was generally understood to extend the criminal provisions of the

government to seek to enjoin individuals from committing health care fraud, *id.* § 5435 (seeking to amend 18 U.S.C. § 1345), and sought to amend the grand jury disclosure rules to allow government prosecutors in criminal cases to disclose information obtained via grand jury for use in civil health care fraud investigations, *id.* § 5436. It also proposed various changes to the civil Stark Law and Civil Monetary Penalties Law, and the Secretary of Health and Human Services' exclusion authority. Stark Laws, 42 U.S.C. § 1395(n)(n) (§ 4042), Civil Monetary Penalties, 42 U.S.C. § 1320(a)-(7)(a)(a) (§ 4043), Exclusion (§ 4044).

[56] 18 U.S.C. §§ 1341, 1343.

[57] *See* Janet Reno, Att'y Gen., U.S. Dep't of Just., Remarks at Press Conference (Sept. 15, 1993) (stating that DOJ was "evaluating measures to increase the Federal power to fight fraud and abuse, for example by strengthening anti-kick-back laws and making heavy penalties against defrauding the Government applicable to those who defraud the private health care system as well."). As noted, GAO had also expressed support for an expansion of the Anti-Kickback Statute. *See, e.g.*, *supra* notes 41 to 43.

[58] H.R. 3600, 103d Cong. § 4041(a)(3) (1993).

[59] *Id.* § 4041(b) (proposing changes to discount, payments to employees, and seeking to introduce new safe harbors for individuals or entities receiving assistance under a grant or cooperative agreement for the provision of health care services and for capitated payments).

[60] *Id.* § 4041(e)(5); United States v. Greber, 760 F.2d 68, 69 (3d Cir. 1985).

Anti-Kickback Statute to private payers.[61] However, as then-Senator Biden noted during hearings,[62] the language of the HSA did not clearly support that understanding.[63]

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[61] Commentators often described the HSA in this way. *See, e.g.*, NCHAA General Counsel Mem. on HSA, *supra* note 53, at 124 ("Because of the other sections of the bill that incorporate these changes to the Social Security Act, the anti-kickback provisions also will apply to all health claims, not just government claims. This will provide a significantly increased ability for private carriers to attack kickbacks related to privately insured services."); Alexander, *supra* note 53, at 113 (citing to Section 5412(a)(1) of the HSA for the proposition that "the HSA would extend . . . the federal anti-kickback statute, Social Security Act § 1128A(a), to all health care payers."); Mike McKee, *Plans on Health Fraud Appear Ill-Fated*, THE RECORDER (California), Sept. 4, 1993 ("For starters, Clinton's American Health Security Act would extend the government's anti-kickback statutes to all health care providers, not just those involved with Medicare and Medicaid, as it works now."). However, these articles appear to be referring to proposed changes to the *civil* monetary provisions section, housed in Section 1128A(a) of the Social Security Act, rather than the Anti-Kickback Statute, which is housed in Section 1128B(b). *See* H.R. 3600, 103d Cong. § 5412(a)(1) (1993).

[62] *Health Care Fraud: Examining Federal, State, and Local Efforts to Combat Fraud and Abuse in the Health Care Industry and Related Provisions of the Proposed Health Security Act, Hearing Before the Committee on the Judiciary,* 103d Cong. 24 (1994) (In response to questioning from then Senator Biden, Gerald M. Stern, Special Counsel, Health Care Fraud, and Special Counsel, Financial Institution Fraud, U.S. Department of Justice, noted that the HSA needed to be "clarified" to make clear that the anti-kickback provisions refer to all-payers).

[63] The primary support for the common interpretation appears to be based on Title V., Subtitle E, Part 2 of H.R. 3600, which is entitled "Application of Fraud and Abuse Authorities Under the Social Security Act to *All Payer*s." *See* H.R. 3600 (emphasis added). However, it only discusses changes to the exclusion and civil monetary penalty sections. *Id.* Further, a subsequent congressional committee summarizing bipartisan efforts to expand the Anti-

3. Other Efforts

Almost simultaneously, and in some instances even before President Clinton introduced the HSA, Democrats and Republicans introduced competing health reform bills.[64] Significantly, many of these bills proposed expanding the Anti-Kickback Statute to cover other government health insurance plans, as well as private health insurance plans.

i. 103rd Congress (1993 to 1994): Senate and House Propose Broad and Limited Expansions

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Kickback Statute to cover private payers, did not include the HSA in that summary. *See* H.R. REP. No. 104-747, at 5 (1996). The HSA also included proposed expansions of the administrative exclusion and civil monetary penalties for violations of the Anti-Kickback Statute to all health plans, with that term defined under the statute to include private health plans. Sections 5411 (addressing exclusion) and 5412 (addressing civil monetary penalties) refer to "any applicable health plan." The HSA defines "health plans" to include private payers. *See* H.R. 3600, 103d Cong. § 1400; H.R. 3600, 103d Cong. Subtitle E, Pts. 2-4; *id.* § 5412(a)(1) (addressing changes to 42 U.S.C. § 1320a-7a(a), Civil Monetary Penalties Law); *id.* § 5421 (referring reader to Section 4041 for "provisions amending the anti-fraud and abuse provisions existing under the Social Security Act"); *id.* § 4041(a) (amending penalties to Civil Monetary Penalties and Anti-Kickback provisions); *id.* § 4041(b) (amending safe harbor provisions exceptions).

[64] *See, e.g.*, The American Health Security Act of 1993, H.R. 1200, 103d Cong. (1993) (proposing a single-payer insurance system); The Managed Competition Act of 1993, H.R. 3222, 103d Cong. (1993) (proposing that employers be required to offer insurance but not be required to finance the insurance); The Health Equity and Access Reform Today Act of 1993, S. 1770, 103d Cong. (1993) (proposing the requirement that all individuals purchase insurance and all employers offer employees a health plan). *See also* U.S. GOV'T ACCOUNTABILITY OFF., GAO/RCED-94-240, REPORT TO CONGRESSIONAL REQUESTERS ON SMALL BUSINESS: SBA'S HEALTH CARE REFORM ACTIVITIES (1994), https://www.gao.gov/assets/rced-94-240.pdf.

The 103rd Congress featured bills proposing broad expansions of the Anti-Kickback Statute to private insurance plans (which will be referred to as "broad expansions"), as well as proposals for limited expansions to just government insurance plans (which will be referred to as "limited expansions").

a. Senator Cohen's S.867 Proposed a Broad Expansion[65]

Senator William Cohen, a Republican senator from Maine led much of the effort to strengthen health care fraud laws.[66] His efforts prominently featured a proposal to extend the Anti-Kickback Statute to private payers.

On May 4, 1993, just shortly after President Clinton took office, Senator Cohen introduced S.867, the National Health Care Anti-Fraud and Abuse Act of 1993.[67] It had five co-sponsors, four Republicans,

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[65] Prior to S. 867, in March 1993, Senator Paul Wellstone (D-MN) introduced S. 491, The American Health Security Act of 1993. It proposed a narrower extension of the Anti-Kickback Statute's criminal penalties to "State health security programs" and not just State medical assistance programs like Medicaid. S. 491, 103d Cong. § 411 (1993). Its counterpart in the house was H.R. 1200, the American Health Security Act of 1993.

[66] *See, e.g.*, *Medicare Fraud & Abuse: Hearing Before the S. Comm. on Finance*, 104th Cong. 16-17 (1995) (statement of Sen. Bob Packwood, Chairman, Spec. Comm. on Finance stating that Sen. Cohen had done "yeoman work" on health care fraud issues). In his comments, Senator Cohen gives credit to the late Senator Jack Heinz for doing the initial work. *Id.* Senator Cohen served as Chairman of the Committee from 1995 to 1996. *U.S. Senate, Spec. Comm. On Aging,* Past Chairmen, https://www.aging.senate.gov/about/senator-william-cohen (last visited Mar. 15, 2023).

[67] The National Health Care Anti-Fraud and Abuse Act of 1993, S. 867, 103d Cong. (1993).

and one Democrat.[68] That bill focused primarily on extending the penalties for fraud and abuse that applied to Medicare and State health care programs, to "all health care plans."[69] But, it also included a proposal to extend the Anti-Kickback Statute to cover private insurance plans.[70] In proposing the legislation, Senator Cohen repeated many of the points that were made in the GAO reports, stating:

> Many fraudulent activities target both government programs and private payers and much more coordination of enforcement efforts is necessary. Most types of fraud could be avoided by closing loopholes that exist in current law or in Medicare rules and regulations and by extending prohibitions that now exist in Medicare to private insurance situations.[71]

[68] Senator Richard Lugar (R-IN), Senator Carl Levin (D-MI), Senator Alan Simpson (R-WY), Senator John Danforth (R-MO) and Senator Chuck Grassley (R-IA). They joined as co-sponsors on different dates between June 1993 and October 1993. *S. 867 - National Health Care Anti-Fraud and Abuse Act of 1993*, *Cosponsors*, CONGRESS.GOV, https://www.congress.gov/bill/103rd-congress/senate-bill/867/cosponsors?s=4&r=18 (last visited Apr. 21, 2023).

[69] S. 867, 103d Cong. (1993) (listing the purpose of the bill "[t]o amend title XI of the Social Security Act to extend the penalties for fraud and abuse assessed against providers under the medicare program and State health care programs to providers under all health care plans, and for other purposes.").

[70] *See id*. § 102(b)(1)(A) (amending the Anti-Kickback Statute to include "health plans"); *id.* § 102(c)(i) (defining "health plans" to cover private insurance plans); *see also* 139 CONG. REC. 8963, 9106 (1993).

[71] 139 CONG. REC. 8963, 9104 (1993).

S.867 did not get much traction. It was referred to, but did not emerge from, the Committee on Finance.[72]

b. Representative Michel's H.R. 3080 Proposes Broad Expansion

On September 15, 1993, a few days before President Clinton's speech to the Joint House Session, Representative Bob Michel (R-IL) and approximately 100 other Republicans introduced H.R. 3080, the Affordable Health Care Now Act of 1993.[73] Among other things, the Act proposed to extend the Anti-Kickback Statute to cover private

[72] *S.867 - National Health Care Anti-Fraud and Abuse Act of 1993*, *Actions*, CONGRESS.GOV, https://www.congress.gov/bill/103rd-congress/senate-bill/867/all-actions?s=4&r=18 (last visited Apr. 21, 2023).
[73] The Affordable Health Care Now Act of 1993, H.R. 3080, 103d Cong. (1993).

insurance plans.[74] Both the House and identical Senate versions were co-sponsored by multiple Republicans,[75] but neither version passed.[76]

c. Senator Cohen's Senate Amendment 1107 Does Not Propose Expansion

On November 5, 1993, shortly before President Clinton's HSA was introduced in Congress, Senator Cohen proposed Senate Amendment 1107—also titled the National Health Care Anti-Fraud and

[74] H.R. 3080, 103d Cong. § 2314(b)(1)(B)(ii) (1993) (amending the Anti-Kickback Statute, 42 U.S.C. § 1320a–7b(a)(1), by extending it to cover not just government health care plans, but also "health benefit plans" as defined in "section 1128(i)"); *id.* H.R. 3080, § 2314(c) (amending Section 1128(i) to define "health benefit plan" to mean "a health benefit program other than the medicare program, the medicaid program, or a State health care program.").

[75] Approximately 34 additional Republican congressional representatives subsequently joined in sponsoring this Act. *See id.* H.R. 3080. Additional sponsors were added to H.R. 3080 on November 17, 1993 and February 4, 1994. Soon after, on October 7, 1993, Senator Trent Lott (R-MS) introduced S. 1533, which was identical to H.R. 3080, in the Senate. S. 1533, 103d Cong. §§ 2314(b)(1)(B)(ii), (c) (1993). Thirteen Republican Senators subsequently joined as co-sponsors. *See Id.* S. 1533; *S.1533 - Affordable Health Care Now Act of 1993*, *Cosponsors,* CONGRESS.GOV, https://www.congress.gov/bill/103rd-congress/senate-bill/1533/cosponsors?s=3&r=1&q=%7B%22search%22%3A%5B%22s.1533%22%5D%7D (last visited Apr. 21, 2023).

[76] *S.1533 - Affordable Health Care Now Act of 1993*, *Actions*, CONGRESS.GOV, https://www.congress.gov/bill/103rd-congress/senate-bill/1533/all-actions?q=%7B%22search%22%3A%22S.1533%22%7D (last visited Apr. 21, 2023); *H.R. 3080 - Affordable Health Care Now Act of 1993*, *Actions*, CONGRESS.GOV, https://www.congress.gov/bill/103rd-congress/house-bill/3080/all-actions?q=%7B%22search%22%3A%22H.R.+3080%22%7D (last visited Apr. 21, 2023).

Abuse Act of 1993—as an amendment to the Violent Crime Control and Law Enforcement Act of 1993, S. 1607.[77]

Although this amendment included many of the proposals in Senator Cohen's subsequent legislation, including creating a new health care fraud statute and allowing for forfeiture of health care fraud proceeds, it did not include S. 867's proposal to extend the Anti-Kickback Statute to cover private payers.[78] This might have been because S. 867 was pending. The Amendment faced some opposition from Democrats who thought it would be better to include it as part of President Clinton's planned comprehensive health care package.[79] It was, however, agreed to in the Senate by a unanimous voice vote.[80] The House ultimately removed the Amendment from the crime bill[81] based on a fear that a larger health care reform package would lose Republican support if fraud provisions were carved out into separate bills.[82]

d. Senator Chafee's S.1770 Proposes Broad Expansion

[77] S. Amdt. 1107, 103d Cong., 139 CONG. REC. 27635–36 (1993). S. Amdt. 1107 had three co-sponsors one Republican and two Democrats, Senators Robert Dole (R-KS), Senator Harry Reid (D-NV), and Senator Jim Sasser (D-TN). 139 CONG. REC. 27720 (1993).

[78] S. Amdt. 1107, 103d Cong., 139 CONG. REC. 27635–36 (1993); *see also* 140 CONG. REC. 26005 (daily ed. Sept. 27, 1994) (Sen. William Cohen and Sen. Joseph Biden speaking).

[79] *See* S. Amdt. 1107, 103d Cong., 139 CONG. REC. 27636–37 (1993).

[80] *S.Amdt.1107 to S.1607, Actions*, CONGRESS.GOV, https://www.congress.gov/amendment/103rd-congress/senate-amendment/1107/actions?s=5&r=1&q=%7B%22search%22%3A%5B%22S.+Amdt.+1107%22%5D%7D (last visited Apr. 21, 2023).

[81] 140 CONG. REC. 26005 (1994) (Sen. William Cohen and Sen. Joseph Biden speaking).

[82] *Id.* at 26006 (statements of Sen. Harkin and Sen. Cohen) (foreshadowing that later efforts to pass the larger health care reform bill would be ultimately unsuccessful).

Less than three weeks later, and two days after Clinton's HSA was introduced, on November 22, 1993, Senator John H. Chafee (R-RI) introduced S.1770, The Health Equity and Access Reform Today Act of 1993.[83] Among other things, it proposed to extend the Anti-Kickback Statute to cover private insurance plans.[84]

e. **Hearings: Witnesses Call for Broad Expansion**

In 1994, Congress held a series of hearings on the HSA that prominently featured testimony and calls to extend the Anti-Kickback Statute's protections to private payers.

On March 17, 1994, subcommittees of the House Committee on Government Operations held a hearing on the HSA.[85] William Mahon, the Executive Director of the NHCAA, who was invited to offer the private sector's perspective on health care fraud and on proposed legislative approaches to the problem spoke in support of expanding the Anti-Kickback Statute to protect private payers.[86] Similarly, Leslie Aronovitz, the Director of Health Financing Issues, Health, Education and Human Services Division, reported to the subcommittees that private sector payers are "even more disadvantaged" than public payers in pursuing wrongdoers, in part because they have fewer legal tools.[87]

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[83] The Health Equity and Access Reform Today Act of 1993, S.1770, 103d Cong. (1993).

[84] *Id.* at § 4102(b)(1) (1993) (amending The Anti-Kickback Statute to also cover "Health Care Plans"); *id.* § 4102(c) (defining "Health Care Plan" as a public or private program for the delivery of or payment for health care items or services other than the Medicare program, the Medicaid program, or a State health care program.").

[85] *The Fraud and Abuse Provisions in H.R. 3600, The "Health Security Act": Hearing on H.R. 3600 Before the Subcomm. on Legis. & Nat'l Sec. and the Subcomm. on Hum. Res. & Intergovernmental Rel. of the H. Comm. on Gov't Operations*, 103d Cong. (1994).

[86] *Id.* (statement of William J. Mahon, Exec. Dir., NHCAA).

[87] *Id.* (statement of Leslie Aronovitz, Assoc. Dir., U.S. Gen. Acct. Off.).

Among other things, she recommended "tighter restrictions to eliminate referral kickbacks in the private sector."[88]

On May 25, 1994, the Senate Judiciary Committee, which then-Senator Biden chaired, held a hearing to discuss the fraud and abuse provisions of the HSA.[89] During the hearing, senators commented that fraud against private insurers ultimately gets passed on to all taxpayers because it causes health care costs and premiums to increase.[90] Mr. Mahon again testified and stated that an obstacle to addressing fraud against private payers is that the Anti-Kickback Statute's protections do not extend to them.[91] A former health care fraud prosecutor with the Department of Justice also testified and echoed that concern.[92] In comments, Senator Biden expressed his support for expanding the Anti-Kickback Statute to private payers, and asked why it did not already, given that so much of the United States health care spending was by private payers.[93] Senator Biden also pushed the General Counsel of the American Medical Association ("AMA") to express a position on expanding the Anti-Kickback Statute.[94] His response was that the AMA

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[88] *Id.* at 29 (testimony of Leslie G. Aronovitz, Assoc. Dir., Health Fin. Issues, Health, Educ. and Hum. Servs. Div.).

[89] *Health Care Fraud: Examining Federal, State, and Local Efforts to Combat Fraud and Abuse in the Health Care Industry and Related Provisions of the Proposed Health Security Act: Hearing Before the H. Comm. on the Judiciary*, 103d Cong. (1994) [hereinafter *1994 Health System Reform Hearing*].

[90] *Id.* at 1, 3 (opening statement of Sen. Biden, Chairman of Judiciary Comm. and statement of Sen. Herbert Kohl).

[91] *Id.* at 111 (statement of William J. Mahon, Exec. Dir., NHCAA).

[92] *Id.* at 103 (statement of Kevin M. Mattessich, Morrison, Mahoney and Miller, former trial att'y and health care fraud prosecutor, Crim. Div., U.S. Dep't of Just.).

[93] *Id.* at 23–24 (statement of Sen. Biden questioning Special Couns. Stern); *see supra* note 62 and accompanying text (Stern conceding that the HSA did not clearly expand the Anti-Kickback Statute to cover private payers).

[94] *Id.* at 107 (statement of Sen. Biden questioning Kirk B. Johnson).

did not object to "broaden[ing]" the Anti-Kickback Statute to cover private payers but was more so concerned that the statute should be structured such that it does not capture legitimate business practices.[95]

f. **Senator Cohen's Minority Staff Gaming Report Recommends Broad Expansion**

Next, following a year-long investigation led by Senator Cohen, on July 7, 1994, the Minority Staff of the Senate Special Committee on Aging issued an investigative staff report entitled *Gaming the Health Care System: Billions of Dollars Lost to Fraud & Abuse Each Year* (the "Gaming Minority Report").[96] The Gaming Minority Report made several findings on the "[d]eficiencies in the current system," one of which was that there were "inadequate tools available to prosecutors." [97] Of note, it recommended that Congress "[i]mprove the anti-kickback statute and extend prohibitions of Medicare and Medicaid to private payers."[98]

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[95] *Id.* at 107–08 (testimony of Kirk B. Johnson, JD, Gen. Couns., AMA).

[96] *Gaming the Health Care System: Trends in Health Care Fraud: Hearing Before the Spec. Comm. on Aging, U.S. Senate*, 104th Cong. 1 app. at 169-93 (1995).

[97]

> Federal prosecutors now use traditional fraud statutes, such as the mail and wire fraud statutes, the False Claims Act, false statement statutes, and money laundering statute to prosecute health care fraud. Our investigation found that the lack of a specific federal health care fraud criminal statute, inadequate tools available to prosecutors, and weak sanctions have significantly hampered law enforcement's efforts to combat health care fraud.

Id. at 171.

[98] *Id.* at 172; *see also id.* at 192 ("Improve the anti-kickback statute and extend prohibitions of Medicare and Medicaid to private payers. Specifically, expand current Medicare and Medicaid anti-kickback statute to

g. **Senator Cohen's Senate Amendments 2593 and 2594**

Subsequently, in late 1994, Senator Cohen introduced two amendments to pending legislation—both of which proposed extending the Anti-Kickback Statute to private payers. Specifically, on September 27, 1994, he proposed Senate Amendment 2593, which sought to amend the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act.[99] The next day, on September 28, 1994, he proposed Senate Amendment 2594, an amendment to a Washington D.C. appropriations bill.[100] Several senators convinced Senator Cohen to withdraw his amendments to avoid delaying the appropriations bills, and he did so very shortly after submitting them.[101]

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private payers and to all federal health care programs; provide civil monetary penalties for anti-kickback violations; and provide injunctive relief for anti-kickback violations."). As set out in the discussion on the 104th Congress, the full Committee began hearings in March 1995 and they echoed these recommendations. *See infra* Part III.A.3.ii.c.

[99] S. Amdt. 2593, 103d Cong. § 102 (1994) (proposed as an amendment to H.R. 4606, 103d Cong. (1994)); *see also* 140 CONG. REC. S26004 (daily ed. Sept. 27, 1994) (statement of Sen. William Cohen).

[100] S. Amdt. 2594, 103d Cong. § 102 (1994) (proposed as an amendment to H.R. 4649, 103d Cong. (1994)); *see also* 140 CONG. REC. S13589 (daily ed. Sept. 28, 1994) (statement of Sen. Cohen).

[101] 140 CONG. REC. S26009 (daily ed. Sept. 27, 1994) (statement of Sen. Cohen withdrawing S. Amdt. 2593); 140 CONG. REC. S27003 (daily ed. Sept. 30, 1994) (on behalf of Sen. Cohen, Sen. Mitchell withdrawing S. Amdt. 2594); *see also* 141 CONG. REC. S.1219 (daily ed. Jan. 19, 1995) (statement of Sen. Cohen: "On a number of occasions, I sought to attach the provisions to pending legislation, for example, the D.C. appropriations bill and the Labor, HHS appropriations bill. I was prevailed upon to withdraw the legislation at that time so as to allow the appropriations bills to go forward."). Of some note, in October, Rep. John Conyers, Jr. (D-MI) introduced H.R.

ii. 104th Congress (1995 to 1996): Senate Proposes Broad, then Limited, Expansions

Efforts to expand the Anti-Kickback Statute to private payers continued into the 104th Congress, with Senator Cohen taking the lead in most efforts.

a. Senator Cohen's S.245 Proposes Broad Expansion

On January 19, 1995, Senator Cohen introduced the Health Care Fraud Prevention Act of 1995, S. 245, which had bipartisan support.[102] Among other things, and like S.867 and the 1995 Amendments Senator Cohen had put forward, S. 245 proposed to expand the Anti-Kickback Statute to apply to private health plans.[103] On August 1, 1995, an identical bill, H.R. 2151, was introduced in the House.[104] Both the

5258, the Health Fraud and Abuse Act of 1994, but it did not contain kickback (or fraud criminal statute) provisions and focused on authority to conduct audits, investigations, inspections, and evaluations relating to the prevention, detection, and control of health care fraud and abuse. *See* H.R. 5258, 103d Cong. (1994).

[102] Eight of the 21 co-sponsors were democrats. *S.245 – Health Care Fraud Prevention Act of 1995, Cosponsors,* CONGRESS.GOV, https://www.congress.gov/bill/104th-congress/senate-bill/245/cosponsors?s=6&r=1&q=%7B%22search%22%3A%5B%22S.245%22%5D%7D (last visited Apr. 21, 2023).

[103] S. 245, 104th Cong. § 102(a)(1)(A) (1995) (extending the AKS to cover "health plans"); *Id.* § 102(b) (defining "health plans" to include private health insurance plans).

[104] *H.R.2151 – Health Care Fraud Prevention Act of 1995*, *Actions*, CONGRESS.GOV, https://www.congress.gov/bill/104th-congress/house-bill/2151/related-bills?s=9&r=4+%28last+visited+Apr.+21%2C+2023%29.&q=%7B%22search%22%3A%5B%22H.R.+2151%22%5D%7D (last visited May 1, 2023).

Senate and House bills were referred to committees, with no subsequent action reported.[105]

b. Hearings: Witnesses Primarily Call for Broad Expansion

On March 21, 1995, following up on the Gaming Minority Report, the Senate Special Committee on Aging, which Senator Cohen then chaired, held a hearing entitled *Gaming the Health Care System: Trends in Health Care Fraud*.[106] The hearing featured testimony from various federal agency representatives many of whom informed the Committee members that kickbacks were a common feature of health care fraud schemes and expressed the view that the Anti-Kickback Statute needed to be extended to cover private payers.[107]

For instance, in his official statement at the hearings, FBI Director Louis J. Freeh described some of the common health care fraud schemes the FBI had detected.[108] The first scheme he discussed was kickbacks, noting that "kickbacks occur in virtually every segment of

[105] *S.245 – Health Care Fraud Prevention Act of 1995, Actions*, CONGRESS.GOV, https://www.congress.gov/bill/104th-congress/senate-bill/245/all-actions?q=%7B%22search%22%3A%5B%22S.245%22%5D%7D&s=6&r=1 (last visited Apr. 21, 2023); *H.R.2151 – Health Care Fraud Prevention Act of 1995*, *Actions*, CONGRESS.GOV, https://www.congress.gov/bill/104th-congress/house-bill/2151/all-actions?q=%7B%22search%22%3A%5B%22H.R.+2151%22%5D%7D&s=9&r=4 (last visited Apr. 21, 2023).
[106] *See generally Gaming the Health Care System: Trends in Health Care Fraud: Hearing Before the S. Spec. Comm. on Aging*, 104th Cong. (1995).
[107] *See generally id.*
[108] *See id.* at 16-28 (statement of Louis J. Freeh, Dir., Fed. Bureau of Investigations).

the health care system" in both "unsophisticated and complex forms."[109] He added:

> Regrettably, the Federal Anti-Kickback Law only applies when Medicare or Medicaid patients are being treated, and does not explicitly cover other government programs and private insurance plans. Current Federal Law does not explicitly cover other government health care programs. Broader kickback laws are needed with both civil and criminal remedies to cover all federal health care programs and private insurers. [110]

Director Freeh repeatedly emphasized this point throughout his statement. [111] A DOJ report issued around the same time also called for an all-payer approach to health care fraud.[112]

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[109] *Id.* at 21.

[110] *Id.*

[111] *See id*. at 14 (stating that there "are gaps in the law with respect to our ability to conduct investigations at all," and identifying one gap as the absence of a kickback law protecting private payers); *see also id.* at 27 (addressing the FBI's "concerns with existing federal laws," and reiterating that one gap in existing laws is that kickback payments for private insurance services are not covered by the Anti-Kickback statute); *see also id.* at 27 (discussing schemes the FBI had identified in which the perpetrators sought to evade the Anti-Kickback statutes by only paying for services paid for by private insurance programs, again stating that "[r]egrettably, this kickback activity is not directly covered by Federal Law"); *see also id.* at 41 (responding to a question to reiterate that the FBI would like to see the Anti-Kickback Statute improved to cover payments made to induce referrals for private and federal government employee insurance programs).

[112] U.S. DEP'T OF JUST., HEALTH CARE FRAUD REP. FISCAL YEAR 1994 17 (1995).

Shortly after, on June 15, 1995, a subcommittee of the House Committee on Government Reform and Oversight held a hearing entitled *Keeping Fraudulent Providers Out of Medicare and Medicaid*.[113] Witnesses also expressed support for an "all-payer" approach to targeting health care fraud.[114] The NHCAA's Mahon asked Congress "to make illegal in dealings with private and other government payers what today is illegal only in dealings with the Medicare and Medicaid programs."[115]

But, perhaps in a sign of things to come, Gerald Stern, Special Counsel for Health Care Fraud at the Department of Justice limited his ask to "Federal health care plans," stating that "[i]t would be helpful to create a criminal and civil bar on kickbacks in all *Federal* health care plans."[116]

c. **Senator Cohen's S.1088 Proposes Limited Expansion**

Soon after the hearings, on July 28, 1995, Senator Cohen introduced S.1088, the Health Care Fraud and Abuse Prevention Act of 1995.[117] Although S.1088 proposed to revise the Anti-Kickback Statute from applying to just "Medicare or State Health Care Programs," and

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[113] *See generally Keeping Fraudulent Providers Out of Medicare and Medicaid: Hearing Before the Subcomm. on Hum. Res. & Intergovernmental Rels. of the H. Comm. on Gov. Reform and Oversight*, 104th Cong. (1995) [hereinafter *Keeping Fraudulent Providers*].

[114] *Id.* at 100-101 (responses of Jonathan Ratner, Assoc. Dir., Health Finance Issues, GAO, to questioning and agreeing that there were benefits to an "all-payer approach to fraud and abuse").

[115] *Id.* at 85 (statement of William Mahon, Exec. Dir. of NHCAA). He went on to note that it was not "illegal to pay kickbacks for referrals in private-patient dealings, as it is against Medicare and Medicaid." *Id.* at 102.

[116] *Id.* at 50 (testimony of Gerald Stern, Special Couns. for Health Care Fraud at the Dep't of Just.) (emphasis added).

[117] S. 1088, 104th Cong. (1994); 141 CONG. REC. S10,878 (daily ed. July 28, 1995) (statement of Sen. William Cohen).

instead to cover "Federal Health Care Programs," it did not extend the Anti-Kickback Statute's protections to private health insurance programs.[118] S.1088 defined "Federal Health Care Programs" to mean "any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded, in whole or in part, by the United States Government; or ''any State health care program, as defined in 42 U.S.C. 1320a-7(h)."[119] In other words, under S.1088, the Anti-Kickback Statute would extend to other federal health programs such as TRICARE, but not to private health insurance programs. It had seven co-sponsors, the majority of whom were Democrats.[120]

In introducing S.1088, Senator Cohen acknowledged that it was different from S.245 in several respects including that the Anti-Kickback Statute would apply to Federal health care programs (as opposed to all programs), and that the exclusion provisions had been narrowed so that individuals not directly involved in fraudulent activity (*e.g.*, board members of hospitals) would not be penalized.[121] The only explanation that appears to potentially discuss the changes is the following statement:

> Since I introduced S. 245 in January of this year, I have solicited comments on this legislation from a host of law enforcement agencies, health care

[118] S. 1088, 104th Cong. § 102(a)(1)(A) (1994); 141 CONG. REC. S10,879 (daily ed. July 28, 1995) (introduction of S. 1088 by Sen. William Cohen).

[119] S. 1088, 104th Cong. § 102(a)(1)(F).

[120] *S. 1088 – Health Care Fraud and Abuse Prevention Act of 1995, Cosponsors*, CONGRESS.GOV, https://www.congress.gov/bill/104th-congress/senate-bill/1088/cosponsors?s=7&r=1.

[121] 141 CONG. REC. S10,879 (daily ed. July 28, 1995) (introduction of S. 1088 by Sen. William Cohen). The record also includes a section-by-section analysis of changes to S.245. *See id.* at S.10,886 (setting out multiple changes including that the deletion of the requirement that the HHS Inspector General consult with the Attorney General before issuing a special fraud alert).

> provider groups, and experts in criminal law and health care. My purpose in seeking and reviewing comments on my legislation was to ensure that health care fraud legislation be tough on those who intentionally scam or defraud the health care system, but also be fair and workable in practice, and not inadvertently penalize honest health care providers who inadvertently run afoul of complicated health care regulations.[122]

A few days later, on July 31, 1995, the Senate Finance Committee held hearings to examine proposals to reduce fraud, waste and abuse in the Medicare program, including S.1088.[123] It received testimony from Senator Cohen himself, as well as multiple federal agency representatives, including Charles L. Owens, Financial Crimes Section, Federal Bureau of Investigation.[124] In his testimony, Senator Cohen offered a similar explanation:

> Since I introduce[d] S. 245 in January, I have really tried to work with all of the groups who are involved in this, all of the health care providers, law enforcement agencies, to try to strike a balance. The health care industry itself is concerned that this is going to be too tough, that this is legislation which is designed to make

[122] 141 CONG. REC. S10,879 (daily ed. July 28, 1995) (introduction of S. 1088 by Sen. William Cohen).

[123] *Medicare Fraud & Abuse: Hearing Before the S. Comm. on Fin.*, 104th Cong. III (1995) [hereinafter *S. Comm. on Fin. Hearing*].

[124] *Id.* Others who testified included June Gibbs Brown, Inspector Gen., Dep't of Lab. & Hum. Serv.; Sarah F. Jaggar, Dir., Health Fin. & Pol'y Issues, Health, Educ. & Hum. Serv. Div., Gen. Acct. Off., and Paul N. Van de Water, Assistant Dir., Budget Analysis Div., Cong. Budget Off.

> criminals out of innocent mistakes, which
> is not the objective of the legislation.[125]

In light of those concerns, he stated, "I have worked with these groups to make some changes."[126] Although not entirely clear, the reasons he provided for the changes from S. 245 to S. 1088 appear to mainly refer to the changes relating to the exclusion authority.[127]

d. **Hearings: Witnesses Express Support for Broad Expansion**

In a hearing just three months later, Senator Cohen noted that both the FBI and DOJ supported S.1088.[128] In his testimony and follow-up to Congress, Mr. Owens, the FBI White Collar Crimes Section Chief confirmed that statement but went further and expressed support for a broader expansion.[129] He stated that one of the gaps in FBI's tool arsenal is that "The Anti-Kickback Statute is applicable to just the Medicare and Medicaid programs."[130] And in his follow-up written response to the Committee he went further, describing as a "prosecutive stumbling block" that under the current Anti-Kickback Statute, it was not illegal to pay kickbacks to refer services paid for by "other government programs *and private insurance carriers*."[131] The Senate did not take further action on S. 1088.[132]

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[125] *Id.* at 20.

[126] *Id.*

[127] *Id.*; *see* 141 Cong. Rec. S10,879 (daily ed. July 28, 1995) (introduction of S. 1088 by Sen. William Cohen).

[128] *S. Comm. on Fin. Hearing*, *supra* note 123, at 21.

[129] *Id.* at 5-7, 12-16, 80-89 (statement of Charles Owens, White Collar Crimes Section Chief, Fed. Bureau of Investigation).

[130] *Id.* at 7, 87 (statement of Charles Owens, White Collar Crimes Section Chief, Fed. Bureau of Investigation).

[131] *Id.* at 89 (emphasis added).

[132] *S.1088 – Health Care Fraud and Abuse Prevention Act of 1995, Actions,* CONGRESS.GOV https://www.congress.gov/bill/104th-congress/senate-

e. **Representative Schiff's H.R. 2326 Proposes, and Witnesses Support, Broad Expansion**

A few months later, on September 13, 1995, Representative Steven Schiff (R-NM) introduced H.R. 2326, the Health Care Fraud and Abuse Prevention Act of 1995.[133] It had 33 co-sponsors from both parties[134] and proposed a broad expansion of the Anti-Kickback Statute to protect all health care benefit programs, including private insurance programs.[135] This broad expansion received support from the law enforcement community.[136]

On September 28, 1995, a subcommittee of the House Committee on Government Reform and Oversight held a hearing on

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bill/1088/actions?s=1&r=1&q=%7B%22search%22%3A%5B%22s1088%2C+104th%22%5D%7D (last visited Mar. 20, 2023).

[133] Health Care Fraud and Abuse Prevention Act, H.R. 2326, 104th Cong. (1995).

[134] *H.R. 2326 - Health Care Fraud and Abuse Prevention Act of 1994, Cosponsors,* CONGRESS.GOV (last visited Mar. 20, 2023).

[135] H.R. 2326 § 206(b) (proposing new anti-kickback statute under Title 18 that would apply to "health care benefit programs"); *id.* § 201(a), 202 (defining "health care benefit programs" as including both public and private payers). On September 21, 1995, Representative William Thomas (R-CA) introduced H.R. 2389, the Safeguarding Medicare Integrity Act of 1995. It proposed changes to the Anti-Kickback Statute, not including the expansion the private payers. One such change was to alter the intent requirement to require that the government show that the kickback was paid with a significant purpose of inducing" referrals 201(c). That provision was criticized by the DOJ. *See Health Care Fraud and Abuse: Hearing Before the Subcomm. on Hum. Res. & Intergovernmental Rels. of the Comm. on Gov't Reform & Oversight*, 104th Cong. 1, 255 (1995) [hereinafter *Health Care Fraud and Abuse Hearing*] (statement of Andrew Foie, Assistant Att'y Gen., Department of Justice on Medicare Proposals).

[136] *See generally infra* note 140.

H.R. 2326 and another fraud-focused bill.[137] Gerald Stern, Special Counsel on Health Care Fraud and Financial Institution Fraud at the Department of Justice testified in support of an expanded Anti-Kickback Statute, stating:

> 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 resources. In addition, because of the limited coverage of the existing statute, many providers are not deterred by it . . . .[138]

The NHCAA's Mahon applauded the bill for extending the Anti-Kickback Statute to private payers.[139] He also emphasized that limiting the extension to government payers—as proposed by S. 1088—would result in fraud shifting, stating:

> To the extent that anti-fraud efforts limit themselves to Medicare, Medicaid, or

[137] The other bill was H.R. 1850, the Health Care Fraud and Abuse Act of 1995. It was introduced by Representative Edolphus Towns (D-NY) on June 14, 1995, but did not address the Anti-Kickback Statute.

[138] *Health Care Fraud and Abuse Hearing*, *supra* note 135, at 134 (statement of Gerald M. Stern, Special Counsel, Health Care Fraud, Dep't of Just. on the Health Care Fraud and Abuse Prevention Act of 1995). Although H.R 2326's anti-kickback expansions applied to both public and private payers, Mr. Stern described it as expanding its application only to other government payers. *Id.* at 158.

[139] *Id.* at 187–88 (testimony of William Mahon, Exec. Dir., NHCAA).

> Government-program fraud, the likely result will be a fraud-shifting, similar to cost-shifting, in which the providers realize that now it's more dangerous to defraud Government programs, so they are not going to go out of the fraud business, they are going to turn up the heat against private payers.[140]

In a follow-up letter to the committee, Andrew Foie, Assistant Attorney General, DOJ, also called for an expansion of the Anti-Kickback Statute, albeit only explicitly referencing expanding it to government insurance programs but went on to note that the limited reach of the Anti-Kickback Statute creates problems in prosecutions.[141] He stated:

> 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.[142]

iii. 104th Congress (1995 to 1996): Continued Efforts at Expansion (Broad and Limited) End in Veto

A few days later, on September 29, 1995, Senator Bill Archer (R-TX), introduced H.R. 2425, the Medicare Preservation Act of

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[140] *Id.* at 187.

[141] *Health Care Fraud and Abuse: Hearing Before the Subcomm. on Hum. Res. & Intergovernmental Rels., Comm. on Gov't Reform and Oversight*, 104th Cong. 255 (1995) (letter from Andrew Foie, Ass't Att'y Gen., Dep't of Just. to Rep. Christopher Shays, Chairman of Comm., Oct. 6, 1995). In his letter, Mr. Foie was commenting on H.R. 2389, which did not include a kickback expansion provision.

[142] *Id.*

1995.[143] It had eight co-sponsors, all of whom were Republicans.[144] Unlike S.1088, the House bill included a preventing fraud and abuse section, which among other things, proposed to expand the Anti-Kickback Statute to all health care benefit programs, including private insurance programs.[145]

The bill also proposed increasing the intent level for imposing Anti-Kickback Statutes to kickbacks made "for the significant purpose of inducing" referrals or services.[146] The intent standard revision elicited opposition to H.R. 2425 from the Administration and house

[143] H.R. 2425, 104th Cong. (1995) (H.R. 2389, Safeguarding Medicare Integrity Act of 1995, was incorporated, with some changes, into H.R. 2425).
[144] *H.R. 2425 - Medicare Preservation Act of 1995*, CONGRES.GOV, https://www.congress.gov/bill/104th-congress/house-bill/2425/cosponsors (last visited Apr. 1, 2023).
[145] H.R. 2425, 104th Cong. § 15122 (1995) (expanding Anti-Kickback Statute to cover "any health care benefit program"); *id.* (defining health care benefit program as including "any public or private plan or contract under which any medical benefit, item, or service is provided to any individual").
[146] H.R. 2425, 104th Cong. § 15212 (1995); *see also* H.R. REP. NO. 104-276, pt. 2, at 191 (1995)
("This will narrow the application of the anti-kickback provisions to only those situations where inducement was a significant purpose of remuneration.").

democrats.[147] This opposition did not extend to the proposal to extend the Anti-Kickback Statute to cover private insurance plans.[148]

H.R. 2425 eventually morphed into H.R. 2491, The Balanced Budget Act of 1995.[149] The Act adopted the limited version of the Anti-Kickback coverage expansion, extending it to cover all federal health care programs but not private payers.[150] The Balanced Budget Act was

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[147] *See* H.R. REP. NO. 104-276, pt. 2, at 233-35 (letter from Donna E. Shalala, Sec'y of Health & Hum. Servs., Oct. 13, 1995) (expressing "strong opposition" to H.R. 2425, including because it would "relax critical rules that today outlaw kickbacks"); *see also* H.R. REP. NO. 104-276, pt 1, at 461 (citing dissenting views of the Democratic members of the Comm. on Ways & Means); *id.* at 459 (stating that the plan would "[m]ake the existing civil monetary penalty and anti-kickback laws considerably more lenient and place an insurmountable burden of proof on the Government to punish illegal kickbacks to providers"); *House Medicare Bill Overturns Many Stark, Anti-Kickback Provisions*, 4 HEALTH L. REP. (BNA) Oct. 19, 1995, at 1587–88.

[148] *See generally id.*

[149] *H.R. 2425 – Medicare Preservation Act of 1995, Actions,* CONGRESS.GOV https://www.congress.gov/bill/104th-congress/house-bill/2425/all-info?s=5&r=3&q=%7B%22search%22%3A%5B%22H.R.2425+104th%22%5D%7D&titles=hide&actionsOverview=hide&cosponsors=hide&committees=hide&relatedBills=hide&subjects=hide&latestSummary=hide (search H.R. 2425 in 104th Cong., click on "Actions," select "All Actions," review October 26, 1995 entry) (last visited Apr. 21, 2023); *see also* James F. Blumstein, *The Fraud and Abuse Statute in an Evolving Health Care Marketplace: Life in the Health Care Speakeasy*, 22 AM. J. LAW & MED. 205, 227-29 (1996).

[150] H.R. Rep. No. 104-350, at 1181-82 (1995) (Conf. Rep.) (discussing conference agreement to adopt Senate version of expansion); H.R. 2491, 104th Cong. § 8104 (1995); *see* Lisa M. Rockelli, *House/Senate Conf. Budget Bill Alters House Fraud, Abuse Provisions*, 4 HEALTH CARE POL'Y REP. (BNA) Nov. 30 1995, at 1765–66 ("According to a government source, the budget reconciliation bill does not extend the Medicare and Medicaid anti-kickback statute to all payers of health care benefits, but does extend it

passed on November 20, 1995, but was subsequently vetoed by President Clinton on December 6, 1995.[151]

In contrast, according to news reports, President Clinton's then-pending budget proposal included a provision that would have extended the Anti-Kickback Statute to all private payers.[152]

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to other federal health care programs such as the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), the Federal Employee Health Benefits Program, and the Veterans' Administration health care program."). The Act also contained multiple additional criminal law provisions focused on addressing health care fraud. It created a new health care fraud law, 18 U.S.C. § 1347; expanded an existing injunctive relief law to apply to federal health care offenses, 18 U.S.C. § 1345; created a false statements in health care matters statute, 18 U.S.C. § 1033; created an obstruction of criminal investigations of health care offenses statute, 18 U.S.C. § 1518; created a theft or embezzlement in connection with health care statute, 18 U.S.C. § 669; expanded the money laundering statute to include health care offenses, 18 U.S.C. § 1956(c)(7); and created administrative investigative demand procedures, now generally referred to as HIPAA subpoenas, 18 U.S.C. § 3486. *See* H.R. 2491, 104th Cong. §§ 8141–48 (1995). The Conference Report does not explain why the Senate version was adopted.

[151] *H.R. 2491 – Balanced Budget Act of 1995, Actions,* CONGRESS.GOV https://www.congress.gov/bill/104th-congress/house-bill/2491/actions?s=1&r=1&q=%7B%22search%22%3A%5B%22hr2491+104th%22%5D%7D (last visited Apr. 21, 2023). President Clinton subsequently issued a document setting out "82 Selected Issues" explaining his decision to veto. The failure to expand the Anti-Kickback Statute to cover private payers was not one of them. *President Clinton's Reasons for Vetoing the Republican Budget: 82 Selected Issues*, https://clintonwhitehouse3.archives.gov/WH/EOP/OP/html/reasons.html (last visited Feb. 27, 2023).

[152] Lisa M. Rockelli, *Clinton Plan Creates New CMPS, Exclusion Rights to Fight Fraud, Abuse*, 4 HEALTH CARE POL'Y REP. (BNA), Dec. 21, 1995, at 1878 ("Clinton's [health care fraud and abuse plan in its seven-year budget

B. 1996: HIPAA Expands the Anti-Kickback Statute Just to "Federal Health Care Programs" to Avoid Interfering with Managed Care

Although Republicans and Democrats sharply disagreed on many aspects of Clinton's health reform plan, they tended to agree on the need to reform the Country's health care fraud and kickback laws. This consensus led to the drafting and eventual passage of the Health Insurance Portability and Accountability Act of 1996 in the House ("HIPAA").

1. H.R. 3103, HIPAA

In the Spring of 1996, Representative Bill Archer (R-TX) introduced H.R. 3103, HIPAA.[153] It contained multiple provisions addressing the privacy and security of patients' health information. Notably, it also contained multiple proposals to address health care fraud and indeed, has been described as "one of the most expansive changes to federal fraud and abuse laws."[154] Unlike the bills put forward in the 103rd and early 104th Congress, HIPAA ultimately became law. It passed with overwhelming support in the House and Senate and was signed into law by President Clinton on August 21, 1996.[155]

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package] calls for extending the Medicare and Medicaid anti-kickback statute to all federal health care programs and private payers, while HR 2491 would just extend it to all other federal health care programs.").

[153] H.R. 3103, 104th Cong. (1996).

[154] Colleen M. Faddick, *Health Care Fraud and Abuse: New Weapons, New Penalties, and New Fears for Providers Created by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA")*, 6 ANNALS HEALTH L. 77, 79 (1997).

[155] Pub. L. No. 104-191, 110 Stat. 1936 (1996). *See also H.R. 3103 – Health Insurance Portability and Accountability Act of 1996,* CONGRESS.GOV https://www.congress.gov/bill/104th-congress/house-bill/3103?q=%7B%22search%22%3A%5B%22H.R.3103+104th%22%5D%7D&s=3&r=6 (last visited Apr. 21, 2023).

Like many of the previously proposed bills, HIPAA, among other things, created a new health care fraud law, 18 U.S.C. § 1347 that covered both public *and* private health plans. It also expanded an existing injunctive relief law to apply to federal health care offenses, 18 U.S.C. § 1345; created a false statements in health care matters statute, 18 U.S.C. § 1033; created an obstruction of criminal investigations of health care offenses statute, 18 U.S.C. § 1518; created a theft or embezzlement in connection with health care statute, 18 U.S.C. § 669; expanded the money laundering statute to include health care offenses, 18 U.S.C. § 1956(c)(7); created administrative investigative demand procedures, now generally referred to as HIPAA subpoenas, 18 U.S.C. § 3486; and provided for forfeiture in relation to health care offenses.[156] However, as will be discussed in the next subsection, HIPAA did not apply this all-payer approach to the changes it made to the Anti-Kickback Statute.

a. **HIPAA's Limited Expansion**

Significantly, for purposes of this article, HIPAA also expanded the Anti-Kickback Statute, however, like S.1088 and the Balanced Budget Act, the expansion was limited to "federal health care programs."[157] It defined "Federal health care program" as:

> any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded

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[156] H.R. 3103, 104th Cong. §§ 241–250 (1996) (enacted). *Compare* H.R. 2491, 104th Cong. §§ 8141–8148 (1995). Other articles contain a more extensive discussion of the health care fraud related laws resulting from HIPAA, including those on the civil and administrative side. *See, e.g.*, Debra Cohn, *Health Care Fraud Legislation*, 45 U.S. ATT'Y'S BULL. (1997), https://www.justice.gov/sites/default/files/usao/legacy/2007/01/11/usab4502.pdf; Faddick, *supra* note 154, at 79–96; David A. Hyman, *HIPAA & Health Care Fraud: An Empirical Perspective*, 22 CATO J. 151, 155-58 (2002).

[157] H.R. 3103, 104th Cong. § 204 (1996) (enacted); *see also* Cohn, *supra* note 156.

> directly, in whole or in part, by the United States Government (other than the health insurance program [for federal government employees, Federal Employee Health Benefit Program (FEHBP)]); or ''(2) any State health care program, as defined in section 1128(h)."[158]

As reflected in the parenthetical in the definition, the expansion did not extend to insurance provided under federal employee health benefit programs. The history shows that the rationale for this limited expansion was three-fold. First, that FEHBP plans operate like private insurance plans, second that private insurance plans use the managed care model, and third, that managed care systems are less susceptible to kickbacks.[159]

In its report on HIPAA, the Ways and Means Committee noted that it "felt that greater deterrence was needed against fraud and abuse in all of the traditional fee-for-service federal programs in addition to Medicare and Medicaid."[160] It added, however, that:

> [T]he Committee decided that the current anti-kickback statute is not well suited to the Federal Employee Health Benefit

[158] H.R. 3103, 104th Cong. § 204(a)(7) (1996) (enacted).

[159] As set out in *The Devil Made Me Do It: An Argument for Expanding the Anti-Kickback Statute to Cover Private Payers*, this rationale does not fully justify the decision to not extend the Anti-Kickback Statute's protections to private insurance plans, while extending those protections to government health insurance plans. First, most government plans are managed care plans. Second, private plans feature fee-for-service systems. Third, managed care plans are susceptible to kickback conduct. Fourth, recognizing that many government health plans are managed care plans, Congress has already attempted to accommodate concerns regarding the interaction between kickback statutes and managed care through a safe harbor in the Anti-Kickback statute. *See* Dike-Minor, *supra* note 4.

[160] H.R. REP. NO. 104-496, pt. 1, at 83 (1996).

> Program (FEHBP) which operates more like a private sector program with a wide range of primarily managed care options for federal employees. The fee-for-service and entitlement nature of the Medicare program and other federal health programs give rise to potentially fraudulent or abusive practices that are not present in an environment with managed care coverage.[161]

b. **HIPAA's Managed Care Safe Harbor**

In a further reflection of Congress's concern about the interaction between kickback laws and managed care entities, HIPAA also created a new safe harbor in the Anti-Kickback Statute that exempted Medicare health maintenance organizations (HMOs) and entities operating under "risk-sharing arrangements" from the kickback prohibition "because of a belief that kickbacks [would] not be a problem under managed care."[162]

The Ways and Means Committee Report explained that without that change all managed care arrangements "could potentially be deemed unlawful."[163] It stated:

> This is because an essential feature of managed care is the offer of remuneration (in the form of discounting or risk sharing arrangements in exchange for provider access to the health plan's enrollee population. Another common feature of managed care is the offer by

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[161] *Id.*

[162] Sharon L. Davies & Timothy Stoltzfus Jost, *Managed Care: Placebo or Wonder Drug for Health Care Fraud and Abuse?*, 31 GA. L. REV. 373, 373 (1997); *see also* HIPAA § 216 (amending 42 U.S.C. § 1320a-7b(b)(3).

[163] H.R. REP. NO. 104-486, pt. 1, at 91.

> health plans to providers of incentives to encourage adherence to cost-saving measures and practice protocols. There is no assurance that either of these (as well as other arrangements inherent in managed care) are permissible under the anti-kickback law.[164]

Congress instructed the HHS Secretary to promulgate rules safe harbor rules, which it did. [165]

2. Government Reform and Oversight Committee Report Tracks HIPAA

A month before HIPAA passed, on July 25, 1996, the House Committee on Government Reform and Oversight approved and adopted a report entitled Health Care Fraud: All Public and Private Payers Need Federal Criminal Anti-Fraud Protections.[166] Like the Ways and Means Committee Report, this report, although pushing for an all-payer approach to health care fraud, expressed a similar concern about extending kickback laws to cover managed care arrangements. It stated:

> "All payer" provisions should also carefully limit or exclude illegal remuneration, bribery or graft as health care offenses. While applicable to fee for service arrangements like Medicare, these offenses would have, at best, an uncertain impact on managed care programs. Strengthened anti-fraud provisions, particularly those aimed at intentional overutilization, need not, and

[164] *Id.*

[165] 42 C.F.R. § 1001.952(t), (u); *see also* Federal Health Care Programs: Fraud and Abuse; Statutory Exception to the Anti-Kickback Statute for Shared Risk Arrangements, 64 Fed. Reg. 233, 63, 507 (Nov. 19, 1999).

[166] H.R. REP. NO. 104-747 (1996).

> should not be in conflict with legitimate managed care arrangements.[167]

Accordingly, at the point, the criminal anti-kickback laws extended to government health plans (albeit not all of them) seemingly because of the above-described managed care rationale.

C. 1997: Post-HIPAA Calls for Broad Expansion

Notwithstanding Congress's apparent assessment that private plans should be excluded from the Anti-Kickback Statute's protections, HIPAA did not end the calls from federal law enforcement for a broad expansion. Although lacking a clear congressional backer, those voices continued.[168]

For instance, during a June 1997 hearing before the Senate Permanent Subcommittee on Investigations, Charles L. Owens, Chief of the Financial Crimes Section at the FBI testified that "the kickback statute currently applies only to the public-sponsored programs. It would be helpful to us if there were a kickback provision which applied to the private insurers as well."[169]

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[167] *Id.* at 13–14.

[168] After the passage of HIPAA, The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), proposed to expand HIPAA's anti-fraud and abuse measures (including increasing civil monetary penalties for kickbacks) but did not include a proposal to expand the Anti-Kickback Statute to private payers. *See Hearing Before the Subcomm. on Ways & Means on Health Care Waste, Fraud, and Abuse*, 105th Cong. 1, 2 (1997) (announcement from Congressman Bill Thomas (R-CA) on Health Care Waste Fraud and Abuse hearing) (describing the budget's proposals); Balanced Budget Act of 1997, H.R. 2015, 105th Cong., § 4304 (1997).

[169] *Medicare at Risk: Emerging Fraud in Medicare Programs, Hearing Before the Permanent Subcomm. on Investigations of the S. Comm. on Governmental Affairs*, 105th Cong. 1, 27 (1997).

Subsequently, in October, in testimony before a subcommittee of the House Ways and Means Committee, he again called for a broader kickback law, stating:

> The FBI and other Department of Justice components would support an amendment to the Federal criminal code to create a new generalized offense against kickbacks paid in connection with a "Health Care Benefit Program'' as defined in 18 U.S.C. Sec. 24 (B). This provision would fill the gap in the law by extending Federal anti-kickback criminal sanctions to all Health Care Benefit Programs, public and private."[170]

Beyond that, however, things were relatively quiet on the question of the reach of the Anti-Kickback Statute's coverage until approximately 2010 when the Obama Administration began its push for health reform.

IV. THE 2010 PATIENT PROTECTION AND AFFORDABLE CARE ACT APPEARS TO EXTEND THE ANTI-KICKBACK STATUTE TO COVER EXCHANGE PLANS

The 2010 Patient Protection and Affordable Care Act or the Affordable Care Act ("ACA")[171] as it is more commonly known, made a few changes relating to the Anti-Kickback Statute, but—notwithstanding language that suggested otherwise—none that expanded its coverage. Specifically, it made the Anti-Kickback Statute a predicate offense under the civil False Claims Act, and clarified the

[170] *Health Care Waste, Fraud, & Abuse: Hearing Before the Subcomm. on Health of the Comm. on Ways & Means, H.R.*, 105th Cong. 1, 80 (1997) (prepared statement of Charles L. "Chuck" Owens, Chief, Financial Crimes Section, FBI).

[171] The Patient Protection and Affordable Care Act (Affordable Care Act), Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified as amended in scattered sections of 42 U.S.C.).

Statute's intent requirements.[172] It also instructed the U.S. Sentencing Commission to provide for increased penalties in the Sentencing

[172] Affordable Care Act § 6402(f), 124 Stat. 759 (making the Anti-Kickback Statute a predicate offense of the False Claims Act change); § 10606(b), 124 Stat. 1006 (codified in 28 U.S.C. § 994) (addressing intent requirement by inserting: "a person need not have actual knowledge of this section or specific intent to commit a violation of this section"). The False Claims Act is a civil law that imposes civil liability on persons who knowingly submit a false or fraudulent claim or engage in various types of misconduct involving federal government money or property. *See* 31 U.S.C. § 3729 *et seq.* It is used to prosecute fraud against Medicare and Medicaid. *Id.* ACA made other changes to health care fraud laws. *See* Jeffrey B. Hammond, *What Exactly is Healthcare Fraud after the Affordable Care Act*, 42 STETSON L. REV. 35 (2013). Although ACA did not expand the Anti-Kickback Statute, it put in place the Physician Payments Sunshine Act (the "Sunshine Act"), 42 U.S.C. § 1320(a)-(7)(h), which had been pushed for several years by Republican Senator Chuck Grassley and Democratic Senator Herb Kohl. 42 U.S.C. § 1320a-7h. The Sunshine Act is a transparency law that requires certain manufacturers of drugs, medical devices, and biological and medical supplies covered by Medicare, Medicaid, or the Children's Health Insurance Program, to collect and report to the Centers for Medicare and Medicaid Services ("CMS") financial relationships with "covered recipients," which includes physicians, teaching hospitals and various other providers. *Id.* (The PPSA was updated by the SUPPORT for Patients and Communities Act of 2018, Pub. L. No. 115-271, 132 Stat. 3894, § 6111, to among other things, expand the types of providers that qualify as "covered recipients" to include physician assistants and other providers.) CMS then makes this information available on a public and searchable website, now referred to as Open Payments. The goal of the Act was to bring "transparency to the financial relationships that exist between the drug and device industries and doctors" in an effort to ensure that physicians make decisions based not on payments, but rather what was in the best interests of their patients. 153 CONG. REC. S11,218 (daily ed. Sept. 6, 2007) (statement of Sen. Charles Grassley, IA); *see also* 154 CONG. REC. S2320 (daily ed. Apr. 2, 2008) (statement of Sen. Charles Grassley, IA); 155 CONG. REC. S787 (daily ed. Jan. 22, 2009)

Guidelines for health care fraud offenses involving certain amounts of fraud on government health care programs.[173]

Aspects of ACA suggested that it might have extended the reach of the Anti-Kickback Statute. One of the primary features of ACA—focused on addressing health care insurance coverage—was the creation of marketplaces ("Exchanges") for individuals to purchase qualified health plans ("QHPs").[174] In addition, ACA provided that individuals could receive premium tax credits and cost-sharing subsidies to purchase these QHPs. Accordingly, because the Anti-Kickback Statute defines "federal health programs" 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 a State health care program,"[175] some (reasonably) assumed QHPs would be subject to the Anti-Kickback Statute.[176]

However, the Obama Administration took a different approach. In response to questions from Representative Jim McDermott, the Secretary for Health and Human Services Katherine Sebelius issued a

(statements of Sens. Charles Grassley, IA and Herb Kohl, WI). For a fuller discussion of the Sunshine Act, including existing state laws and its legislative history, *see* ABRAHAM GITTERMAN ET AL., WHAT IS . . . THE PHYSICIAN PAYMENTS SUNSHINE ACT OR "OPEN PAYMENTS"? (2015).

[173] Affordable Care Act § 10606(a) (codified at 42 U.S.C. 994).

[174] Affordable Care Act §§ 1301-04, 1401-02 (codified at 42 U.S.C. § 18021 and 26 U.S.C. § 36); s*ee also Summary of the Affordable Care Act*, KFF (Apr. 25, 2013), https://www.kff.org/health-reform/fact-sheet/summary-of-the-affordable-care-act/.

[175] 42 U.S.C. § 1320a-7b(b) (emphasis added).

[176] *See, e.g.*, Letter from Rep. Jim McDermott, U.S.H.R., to Sec'y Kathleen Sebelius, U.S. Dep't of Health & Hum. Servs. (Aug. 6, 2013), https://webarchive.loc.gov/all/20131107175912/http://mcdermott.house.gov/images/Letter%20August%206%202013.pdf.

letter stating that the Anti-Kickback Statute did not apply to QHPs.[177] In her letter, the Secretary did not make clear how HHS arrived at that opinion, and simply stated that it reached it "in consultation with the Department of Justice," was based upon a "careful review" of the statutory term "Federal health care program," and included an analysis of all aspects of each program offered under ACA.[178]

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[177] Letter from Sec'y Kathleen Sebelius, United States Dep't of Health & Hum. Servs., to Rep. Jim McDermott, United States (Oct. 30, 2013), https://webarchive.loc.gov/all/20131107175923/http://mcdermott.house.gov/images/The%20Honorable%20Jim%20McDermott.pdf (stating that HHS "does not consider QHPs, other programs related to the Federally-facilitated Marketplace, and other programs under Title I of the Affordable Care Act to be federal health care programs," and thus are not within the scope of the federal anti-kickback statute).

[178] Letter from Sec'y Kathleen Sebelius, U.S. Dep't of Health & Hum. Servs., to Rep. Jim McDermott, U.S.H.R. (Oct. 30, 2013), https://webarchive.loc.gov/all/20131107175923/http://mcdermott.house.gov/images/The%20Honorable%20Jim%20McDermott.pdf (stating that HHS "does not consider QHPs, other programs related to the Federally-facilitated Marketplace, and other programs under Title I of the Affordable Care Act to be federal health care programs," and thus are not within the scope of the federal anti-kickback statute).; *see also* Robert Radick, *The Anti-Kickback Statute and The Affordable Care Act: A Law Enforcement Tool Suddenly Goes Missing*, FORBES (Nov. 13, 2013, 10:28 AM), https://www.forbes.com/sites/insider/2013/11/13/the-anti-kickback-statute-and-the-affordable-care-act-a-law-enforcement-tool-suddenly-goes-missing/?sh=62d8646b1cea. To add to the confusion, ACA has a provision specifically addressing the applicability of the False Claims Act to QHPs. It states: "[p]ayments made by, through, or in connection with an Exchange are subject to the False Claims Act . . . if those payments include *any* Federal funds." Patient Protection and Affordable Care Act § 1313(a)(6), 42 U.S.C. § 18033(a)(6) (emphasis added). As one commentator noted, this provision places "the issuers of QHPs and healthcare providers directly in the line of FCA fire." W. Bruce Shirk, *Health Benefit Exchanges: False Claims Gold Mines?*, HEALTH CARE FRAUD REP. (BNA), May 15, 2013, at 3. Because

Some in Congress disagreed with that interpretation.[179] In a Finance Committee hearing, Senator Grassley questioned Secretary Sebelius about the agency's interpretation that the Anti-Kickback Statute did not cover QHPs. He emphasized that the purpose of the Anti-Kickback Statute (and other fraud statutes) was to protect taxpayers from fraud.[180] Secretary Sebelius did not explain the agency's analysis beyond stating that it concluded that health insurance plans offering insurance on or off the exchanges should be treated the same.[181]

ACA also made Anti-Kickback Statute a predicate offense under the civil False Claims Act, Patient Protection and Affordable Care Act § 6402(e), 42 U.S.C. § 18033 would appear to subject QHPs and health care providers to liability under the FCA if the underlying conduct involved kickbacks. Therefore, although Secretary Sebelius and DOJ concluded that a QHP is not subject to Anti-Kickback Statute, § 18033 would seem to allow the government to use the Anti-Kickback Statute to subject QHPs to liability under the False Claims Statute.

[179] Sen. Chuck Grassley, *Grassley Seeks Answers on Key Anti-Fraud Protections in Obamacare* (Nov. 7, 2013), https://www.grassley.senate.gov/news/news-releases/grassley-seeks-answers-key-anti-fraud-protections-obamacare ("PPACA provides for billions of dollars in subsidies to be paid directly to insurance companies. These taxpayer dollars should be subject to the full arsenal of civil and criminal anti-fraud protections provided by Congress.").

[180] *Health Insurance Exchanges: An Update from the Administration: Hearing Before the S. Fin. Comm.*, 113th Cong., 15–16 (2013). Sen. Grassley asked similar questions at other hearings. *President's Fiscal Year 2015 Health Care Proposals: Hearing Before the S. Fin. Comm.*, 113th Cong. 17 (2014); *Oversight of the U.S. Dep't of Justice: Hearing Before the S. Judiciary Comm.*, 113th Cong. 4, 13 (2014).

[181] *Health Insurance Exchanges: An Update from the Administration: Hearing Before the S. Fin. Comm.,* 113th Cong., 15–16 (2013). That said, recognizing the reality of fraud against private payers, the Obama Administration also launched the Health Care Fraud Prevention Partnership (HFPP), a partnership between federal and state agencies, private insurers,

And so it was that the ACA Anti-Kickback Statute expansion chapter ended. Thus, the state of the Anti-Kickback Statute's coverage today is that it applies only to federal health care benefit programs. Many in law enforcement (and the health care industry more broadly) accepted that health care kickback laws applied only to government health plans. But then, along came the Eliminating Kickbacks in Recovery Act of 2018 ("EKRA"), a new criminal anti-kickback law.

V. THE 2018 ELIMINATING KICKBACKS IN RECOVERY ACT ("EKRA") EXTENDS KICKBACK PROTECTIONS TO PRIVATE INSURANCE PLANS—BUT ONLY FOR CERTAIN SERVICES

EKRA was born out of congressional efforts to address the opioid crisis. It had widespread bi-partisan congressional support and was presented through multiple and very similar bills.[182] EKRA

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states, and associations to exchange information and best practices across the public and private sectors in order to prevent and detect health care fraud. *Fact Sheet: The Health Care Fraud and Abuse Control Program Protects Consumers and Taxpayers by Combating Health Care Fraud*, U.S. DEP'T OF JUST., OFF. OF PUB. AFFS., (Feb. 26, 2016), https://www.justice.gov/opa/pr/fact-sheet-health-care-fraud-and-abuse-control-program-protects-conusmers-and-taxpayers.

[182] On July 19, 2018, S.3254 was introduced in the Senate. S. 3254, 115th Cong. (2018). On September 25, 2018, H.R. 6878 was introduced in the House. H.R. 6878, 115th Cong. (2018). On September 26, 2018, H.R. 6902, was also introduced in the House. H.R. 6902, 115th Cong. (2018). These bills were largely identical, with a few notable exceptions. Like the final law, H.R. 6878 applied to recovery homes, clinical treatment facilities, or laboratories, while S. 3254 and H.R. 6902 applied only to the first two types of entities. In addition, H.R. 6902 and S. 3254 did not include the Rule of Construction paragraph, specifying that proof of actual knowledge of the statute or specific intent to violate the statute, was not an element of proof. Further, S.3254 applied to a narrower universe of actors. Unlike H.R. 6902 and H.R. 6878, which applied to "whoever" engaged in the prohibited conduct, S. 3254, with respect to the payment or offering conduct, applied

ultimately became law through an amendment to H.R. 6, a bill addressing "opioid use disorder prevention, recovery, and treatment."[183]

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.[184] Like the Anti-Kickback Statute, EKRA contains several safe harbors.[185] EKRA is both narrower and broader than the Anti-Kickback Statute. It is

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only to certain individuals associated with recovery homes or clinical treatment facilities.

[183] H.R. 6, 115th Cong. (version introduced in House on June 13, 2018).; H.Res.1099, 115th Cong., § 1821 (2018). The Support for Patients and Communities Act, was the amendment. H.R. Res. 1099, 115th Cong., § 8121 (2018). The amendment passed by a vote of 393 in favor and eight against. *H.Res. 1099 – Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, Actions*, CONGRESS.GOV https://www.congress.gov/bill/115th-congress/house-resolution/1099/actions?s=4&r=75&q=%7B%22search%22%3A%5B%22H.+Res.+1099+115th%22%5D%7D (search H.Res.1099 in 115th Cong., click on "Actions," then click on "Roll no. 415") (last visited Apr. 23, 2023). The eight votes against were from Representatives Amash (R-MI), Biggs (R-AZ), Gaetz (R-FL), Garrett (R-VA), Gosar (R-AZ), Massie (R-KY), McLintock (R-CA), and Sanford (R-SC). *Id.*

[184] 18 U.S.C. § 220.

[185] 18 U.S.C. § 220(b). EKRA's safe harbors are not identical to those in the Anti-Kickback Statute and indeed differ in one significant way. EKRA does not have a safe harbor for payments to "bona fide employees." This difference has generated concern from the private legal bar. *See e.g.*, Katherine Lauer et al., *Eliminating Kickbacks in Recovery Act: Implications for Lab'y Sales Force Arrangements*, 21 J. HEALTH CARE COMPLIANCE 3, 25, 26 (2019); Alex Mitchell, *The Difference Between EKRA and Anti-Kickback Statute*, INDUS. INSIGHTS (July 20, 2021), https://www.lighthouselabservices.com/the-difference-between-ekra-and-anti-kickback-statute/.

narrower because it applies to only a limited group of services and items (*i.e.*, recovery home, clinical treatment facilities or laboratories). It is broader because it applies to a greater number of health care programs because unlike the Anti-Kickback Statute, it applies to private health care programs.

However, unlike with HIPAA, EKRA's legislative history does not indicate that members of Congress expressed concerns about the interaction between kickback laws and managed care private plans. Indeed, the various proposed EKRA bills were barely discussed. Perhaps the most substantive commentary, came from Representative Frank Pallone, Jr. (D-NJ), who described EKRA as well-intentioned, but not fully thought through. He stated:

> Mr. Speaker, there is one provision that is concerning and that I do want to mention. It did not go through regular order and was not properly vetted. In fact, it was added at the very last minute. That is a proposal by Senator Rubio to create a new criminal antikickback statute. I know this proposal is well-intentioned in addressing the serious problem of patient brokers who are taking advantage of individuals with opioid use disorders and referring them to substandard or fraudulent providers in exchange for kickbacks. This is an issue, but since the bill was introduced last Tuesday night, multiple stakeholders have raised concerns that the language does not do what we think it does. It may have unintended consequences . . . . I hope to get a commitment from [the Chairmen] to work to address any

> technical problems with this provision in the upcoming months.[186]

Representative Pallone does not clarify which stakeholders raised concerns, or even what the concerns were, beyond the vague statement that the "language does not do what we think it does" and may have "unintended consequences."[187] Further, he indicated that his concerns were more "technical" than substantive.[188] Notwithstanding Representative's Pallone's concerns about the lack of adequate vetting, there was no in-depth conversation about EKRA during the House's debates, beyond expressions of support for it by other representatives including references to the need "to establish meaningful penalties for profiteering off other people's pain and addiction through illicit referrals."[189]

Similarly, the Senate barely discussed EKRA. On October 3, 2018, the same date the Senate voted to pass EKRA,[190] Senator Amy Klobuchar explicitly acknowledged that the current kickback laws did not extend to private health insurance plans:

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[186] 164 CONG. REC. H9244 (daily ed. Sept. 28, 2018) (statement of Representative Frank Pallone, Jr. (D-NJ)).

[187] *Id.*

[188] *Id.*

[189] 164 CONG. REC. H9249 (daily ed. Sept. 28, 2018) (statement of Sen. Steve Knight); *see also id.* at H9247 (statement of Sen. Bilirakis regarding the need to address patient brokering). Other bills also sought to address problematic conduct in recovery homes. *See, e.g.*, Sober Home Fraud Detection Act, S. 2828, 115th Cong., 2d Sess. (2018) (noting that this is a bill "[t]o develop and identify indicators of potentially fraudulent and disreputable recovery housing operators . . . .").

[190] *H.R.6 – SUPPORT For Patients and Communities Act, Actions*, CONGRESS.GOV (last visited Apr. 9, 2023). The Senate voted to amend H.R.6 by a vote of 98-1, the lone vote coming from Senator Mike Lee (R-UT). *Id.* at *Record Vote No. 221.* Representative Lee did not explain his vote against during the October 3, 2018 debate.

> Our bill targets unscrupulous actors who prey on patients seeking treatment to exploit their health insurance by making it illegal to provide or receive kickbacks for referring patients to recovery homes and treatment facilities. These kickbacks are already illegal under Federal healthcare plans like Medicare, *but there is no Federal law to prohibit them in private health insurance plans.* When people are struggling with addiction, their focus should be on getting well, not on worrying whether treatment facilities are trying to take advantage of them to make more money. It is simply outrageous. Our bill will crack down on healthcare facilities or providers who try to game the system to take advantage of these vulnerable patients.[191]

She added that the goal was to "go after the bad guys, the people who are trying to get people hooked on these drugs."[192] H.R. 6, which incorporated EKRA, was signed into law by President Trump on October 24, 2018.[193]

With the passage of EKRA, the state of the criminal anti-kickback laws in the United States today is that the two existing criminal kickback laws, although similar in many ways, are also very different. One law, the Anti-Kickback Statute prohibits kickbacks for any referrals, but only if paid for by government health care programs (which do not include FEHBPs or QHPs). The other law, EKRA, prohibits kickbacks for only a limited subset of opioid-related referrals,

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[191] 164 CONG. REC. S6472-73 (daily ed. Oct. 3, 2018) (emphasis added) (statement of Sen. Amy Klobuchar).

[192] *Id.* at S6473.

[193] Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, Pub. L. No. 115-271, § 8122, 132 Stat. 3894, (2018) [hereinafter EKRA].

but applies when the underlying services are paid for by government and private health care programs.[194]

VI. CONCLUSION

"There is no real ending. It's just the place where you stop the story."[195]

The passage of EKRA brings us to the "stop" in this story. The story began with the creation of the Anti-Kickback Statute in order to protect the newly created government health care programs, Medicare and Medicaid from fraud.[196] It continued with the realization by many in Congress and the law enforcement community that health care fraud, including through kickbacks, affects both government and private health programs.[197] Accordingly, in the early 1990s, there were several bipartisan pushes to expand the Anti-Kickback Statute to protect private health programs.[198] Those efforts led to HIPAA's much more limited expansion of the Anti-Kickback Statute to cover other government health programs.[199] The creation of QHPS by ACA subsequently raised additional questions about whether the Anti-Kickback Statute had broader scope.[200] And next, EKRA created a new criminal anti-

[194] Commentators have noted that EKRA likely overlaps with the Anti-Kickback Statute to the extent that both cover clinical laboratories since EKRA does not specify that it covers only clinical laboratories involved in substance abuse testing or treatment. *See, e.g.*, Nick Oberheiden, *6 Impacts of EKRA on Laboratories, Clinics, and Other Treatment Facilities*, X NAT'L L. REV. 345 (2020), https://www.natlawreview.com/article/6-impacts-ekra-laboratories-clinics-and-other-treatment-facilities. That discussion is beyond the scope of this article.

[195] Frank Herbert, an American science fiction author best known for the 1965 novel Dune and its five sequels.

[196] *See supra* Part II.

[197] *See supra* Part III.A.

[198] *See id.*

[199] *See supra* Part III.B.

[200] *See supra* Part IV.

kickback law that covered both government and private health care programs but only for limited services.[201]

EKRA is likely just a "stop" in the story. With health care costs ever on the rise and expected to reach $6.3 trillion by 2028,[202] and with health care fraud estimated to account for between 3% to 10% of that expenditure—$186 billion or $620 billion for 2028—respectively, it is likely that the calls to expand the Anti-Kickback Statute to private insurance plans will be renewed in the law enforcement community, and that this story will continue. This is especially so because, as discussed in the article, Congress showed considerable interest in expanding the Statute to private insurance plans, with law enforcement, and representatives of the plans and providers, supporting those efforts. The passage of EKRA might be just the next step towards a broad expansion of the Anti-Kickback Statute that these groups supported.

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[201] *See supra* Part V.

[202] *NHE Fact Sheet*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Feb. 17, 2023, 2:42 AM), https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet.