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REVISITING HEALTH CARE FRAUD IN THE BIDEN ADMINISTRATION

JOAN H. KRAUSE*

ABSTRACT

Although not one of the Biden administration's initial priorities, health care fraud inevitably will be a major concern. First, the federal government's response to the COVID-19 pandemic—including the disbursement of more than \$175 billion in provider relief funds and the loosening of traditionally strict rules on Medicare reimbursement for telehealth services—has created new opportunities to divert health care funds for fraudulent purposes. Second, President Joseph Biden took office in the midst of the incomplete transition from volume-based to value-based payment in the federal health care programs, which will allow fraud to flourish in the gaps between multiple reimbursement systems. Third, regardless of these developments, prior forms of fraud are likely to continue. Thus, the Biden administration will have no choice but to devote significant resources to fraud enforcement.

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I. INTRODUCTION

Given the crises confronting the United States—from the global COVID-19 pandemic, to the war in Ukraine, to political battles over domestic infrastructure¹—President Joseph Biden could well be forgiven for not singling out health care fraud as an initial priority for his administration. After the last two-and-a-half years, worrying about how federal health care dollars are spent almost seems like a luxury, or at least an issue that can be addressed through retrospective audits at some point in the future. Yet fraud is never far from the health care debate, and for good reason: while emergencies may prioritize the immediate disbursement of government funds, sooner or later (often sooner), officials will need to confirm that the funds are being used for their intended purposes. That pressure to verify proper use of funds is even greater in a time of fiscal uncertainty, when economic need has risen at the same time as fears of a pandemic-generated recession. Whenever health care costs are under debate, fraud concerns are never far behind.²

Health care fraud inevitably will be a major concern for the Biden administration for three key reasons. The first is obvious: the COVID-19 pandemic and the government's response to it.³ That includes not only the federal government's efforts to disburse more than \$175 billion in provider relief funds to hospitals and front-line health care providers to address the economic pressures of the pandemic, but also the loosening of traditionally strict rules on Medicare reimbursement for telehealth services.⁴ Second, President Biden took office in the midst of the incomplete transition from volume-based to value-based payment in the federal health care programs—and one thing we have learned from experience is that when multiple reimbursement systems coexist,

1. DOJ Announces Coordinated Law Enforcement Action to Combat Health Care Fraud Related to COVID-19, U.S. DEP'T JUST. (May 26, 2021), <https://www.justice.gov/opa/pr/doj-announces-coordinated-law-enforcement-action-combat-health-care-fraud-related-covid-19>; *Russia-Ukraine War: Insights and Analysis*, HARV. KENNEDY SCH., <https://www.hks.harvard.edu/russia-ukraine-war-insights-analysis> (last visited Mar. 9, 2022); Katie Lobosco & Tami Luhby, *Here's What's in the Bipartisan Infrastructure Package*, CNN (Nov. 15, 2021), <https://www.cnn.com/2021/07/28/politics/infrastructure-bill-explained/index.html>.

2. See Diana Manos, *GOP Puts Heat on Obama's 'Costly' Medicare Fraud-Fighting Technology*, HEALTHCARE IT NEWS (Dec. 28, 2010, 10:41AM), <https://www.healthcareitnews.com/news/gop-puts-heat-obamas-costly-medicare-fraud-fighting-technology>.

3. See Brooke Henderson, *Covid-19 Vaccine Scams Grow, Leveraging Confusion About How to Get the Shot*, WALL ST. J. (Feb. 23, 2021, 5:30AM), <https://www.wsj.com/articles/covid-19-vaccine-scams-grow-leveraging-confusion-about-how-to-get-the-shot-11614076200>.

4. See Coronavirus Aid, Relief, and Economic Security (CARES) Act, Pub. L. No. 116–136, 134 Stat. 367 (2020); Paycheck Protection Program and Health Enhancement Act, Pub. L. No. 116–139, 134 Stat. 622 (2020); Coronavirus Preparedness and Response Supplemental Appropriations Act, Pub. L. No. 116–123, 134 Stat. 156 (2020); *Medicare Telemedicine Health Care Provider Fact Sheet*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Mar. 17, 2020), <https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet>.

fraud will flourish in the gaps.⁵ Third, regardless of these new developments, existing forms of fraud will continue, particularly in the pharmaceutical industry.⁶ In short, the Biden administration will have no choice but to devote significant resources to fraud enforcement.

Part II of this Article analyzes the effects that different presidential administrations may have on health care fraud enforcement, addressing not only the financial results of enforcement efforts but also changes in anti-fraud rhetoric and evolving enforcement priorities. Part III addresses the specific fraud challenges facing the Biden administration, including COVID-19, the incomplete transition from volume- to value-based payment, and more traditional forms of fraud.

II. PRESIDENTIAL ADMINISTRATIONS AND THE CHANGING PRIORITY OF HEALTH CARE FRAUD

While health care fraud remains a constant baseline concern, the primacy of fraud enforcement as a federal priority has varied by presidential administration.⁷ Some reasons may be political: Republican presidents, for example, have been viewed as more friendly to private industry (including the pharmaceutical lobby) than their Democratic counterparts.⁸ Despite the traditional mantra that Republicans are “tough on crime,” that has not necessarily held true for health care fraud enforcement, at least when that enforcement is spearheaded by Democrats.⁹ Indeed, powerful Republican Senator Charles Grassley opposed some of the Obama administration’s fraud funding requests, arguing that “Medicare fraud data doesn’t support rhetoric or spending to crack down on criminal healthcare fraud.”¹⁰ Yet while there may be some truth to these allegations, they are by no means the entire story.¹¹ Trends

5. Joan H. Krause, *Following the Money in Health Care Fraud: Reflections on a Modern-Day Yellow Brick Road*, 36 AM. J.L. & MED. 343, 350 (2010) (describing factors that allow fraud to flourish in complex billing systems).

6. *See id.* at 353 (describing multi-year focus on pharmaceutical fraud).

7. *See* Ben Penn, *U.S. Attorney Vacancies Collide with Biden Corporate Crime Fight*, BLOOMBERG L. (Dec. 10, 2021, 3:45 AM), <https://news.bloomberglaw.com/us-law-week/u-s-attorney-vacancies-may-slow-biden-corporate-crime-fight>.

8. *See, e.g.*, Ben Casselman & Jim Tankersley, *Looking for Bipartisan Accord? Just Ask About Big Business*, N.Y. TIMES (May 14, 2021), <https://www.nytimes.com/2021/05/14/business/economy/big-business-politics-economy.html> (describing potential changes in attitudes); Lev Facher & Kaitlyn Bartley, *Pharma is Showering Congress with Cash, Even as Drug Makers Race to Fight the Coronavirus*, STAT NEWS (Aug. 10, 2020), <https://www.statnews.com/feature/prescription-politics/prescription-politics/> (noting that 53.5% of donations “went to GOP lawmakers or Republican-aligned groups”).

9. *See, e.g.*, *Republican Views on Crime*, REPUBLICAN VIEWS (Aug. 29, 2015), <https://www.republicanviews.org/republican-views-on-crime/>; Manos, *supra* note 2.

10. Manos, *supra* note 2.

11. *See id.*

in health care fraud enforcement are influenced by many factors, both domestic and global.¹² And while an administration may set priorities, the bulk of enforcement efforts are carried out by career bureaucrats rather than their politically appointed bosses.¹³ As a result, changes in fraud enforcement tend to be incremental rather than rapid.

A. *Key Anti-Fraud Statutes*

Although a number of federal statutes are used to reach fraudulent health care activities, key statutes include the Medicare and Medicaid Anti-Kickback Statute, the Ethics in Patient Referrals Act (Stark Law), and the Civil False Claims Act (FCA).¹⁴ The Anti-Kickback Statute prohibits offering, paying, soliciting, or receiving remuneration to induce someone to refer patients or to purchase, lease, or order any item or service for which payment may be made by a federal health care program.¹⁵ Violation of the statute is a criminal felony, punishable by up to five years in prison and a fine of up to \$25,000, as well as exclusion from the federal health care programs; in the alternative, civil monetary penalties (CMPs) of up to \$50,000 per violation, plus three times the remuneration, may be imposed in an administrative proceeding.¹⁶ The Stark Law is a civil statute designed to prohibit the referral of Medicare and Medicaid patients to health care entities with which the referring physician (or an immediate family member) has a financial relationship through ownership, investment, or compensation.¹⁷ In addition to barring payment for services furnished pursuant to a prohibited referral, the statute imposes CMPs and the threat of exclusion, making the claimant ineligible to participate in any of the federal health care programs.¹⁸

By far the biggest financial recoveries accrue under the FCA, a Civil War-era statute originally enacted to prevent fraud on the Union Army.¹⁹ The basic false claims prohibition imposes liability on a defendant when: (1) the defendant presents or causes to be presented a claim for payment or approval; (2) the claim

12. See, e.g., Henderson, *supra* note 3.

13. Indeed, after nearly eleven months in office, President Biden had yet to fill two-thirds of U.S. Attorneys slots, leaving many districts without (semi)permanent political appointee oversight. Penn, *supra* note 7.

14. Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(a)-(b); Stark Law, 42 U.S.C. § 1395nn(a)(1); False Claims Act (FCA), 31 U.S.C. § 3729.

15. 42 U.S.C. § 1320a-7b(b).

16. § 1320a-7b(a)(1) (fine/imprisonment); § 1320a-7(a) (exclusion); § 1320a-7a(a)(10) (civil monetary penalties).

17. Off. of Inspector Gen., *Fraud & Abuse Laws*, U.S. DEP'T HEALTH & HUMAN SERVS., <https://oig.hhs.gov/compliance/physician-education/fraud-abuse-laws/> (last visited Feb. 23, 2022).

18. § 1395nn(g)(3).

19. 31 U.S.C. §§ 3729-33. For a history of the statute, see Joan H. Krause, *Health Care Providers and the Public Fisc: Paradigms of Government Harm Under the Civil False Claims Act*, 36 GA. L. REV. 121, 128 (2001).

is false or fraudulent; and (3) the defendant's acts are undertaken "knowingly," which includes not only actual knowledge, but also deliberate ignorance or reckless disregard of truth or falsity.²⁰ After June 19, 2020, violators are subject to a civil penalty of \$11,665 to \$23,331 per claim, plus three times the damages the government sustained from the fraud.²¹

A key aspect of the FCA enforcement scheme is that the statute permits civil prosecution not only by the Department of Justice (DOJ) but also by private parties, through a *qui tam* provision that permits a private "relator" to bring suit on the government's behalf; if successful, the relator may receive fifteen to thirty percent of the proceeds.²² Since amendments in 1986 modernized the FCA and made it more lucrative to pursue *qui tam* actions, the number of health care-related suits has grown exponentially: in 2021 there were 388 new *qui tam* cases involving the federal health care programs compared to only three in 1987, resulting in recoveries of over \$1.4 billion.²³ As a result of the *qui tam* provisions, the FCA can be invoked not only by federal prosecutors but also by competitors, employees, and even patients.²⁴ Not only does this vastly increase exposure for health care providers, but it means that a large segment of FCA cases are not, at least initially, controlled by federal prosecutors—and not subject to the current administration's control.²⁵

B. *Fraud by the Numbers*

For all the attention that has been devoted to health care fraud over the years, there remains surprising uncertainty. Critics commonly assert that ten percent of health care expenditures are fraudulent, yet that estimate has little empirical support.²⁶ The Department of Health and Human Services (HHS) has calculated the rate of improper payments in the Medicare fee-for-service program since 1996, although the methodology has varied.²⁷ Since the most recent methodology change in 2011, the error rate did not consistently drop below ten percent until 2017; the rates for fiscal years 2020 and 2021 were lower still,

20. § 3729(a)–(b).

21. § 3802(a)(1); 28 C.F.R. § 85.5 (2021).

22. 31 U.S.C. § 3730(b), (d).

23. U.S. DEP'T OF JUST., FRAUD STATISTICS – OVERVIEW (2021), <https://www.justice.gov/opa/press-release/file/1467811/download>.

24. Joan H. Krause, *Twenty-Five Years of Health Law Through the Lens of the Civil False Claims Act*, 19 ANNALS HEALTH LAW & LIFE SCIS. 13, 15 (2010).

25. *See id.* at 16 (describing *qui tam* suits).

26. *The Challenge of Healthcare Fraud*, NAT'L HEALTHCARE ANTI-FRAUD ASS'N, <https://www.nhcaa.org/tools-insights/about-health-care-fraud/the-challenge-of-health-care-fraud/> (last visited Feb. 16, 2021).

27. CTR. FOR MEDICARE & MEDICAID SERVS., MEDICARE FEE-FOR-SERVICE 2012 IMPROPER PAYMENTS REPORT 11–12 (2012).

reaching less than 6.3%.²⁸ Although the error rate is not in itself a measure of fraud, primarily identifying problems with documentation, it does provide a valuable window into the vulnerabilities of the federal health care programs.²⁹

TABLE 1: HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM RESULTS, 1998-2020³⁰

Fiscal Year	New Criminal Investigations	Defendants Convicted	New Civil Investigations	Exclusions	Total Judgments/Settlements
1998 ³¹	322	326	107	3,021	\$480 million
1999 ³²	371	396	91	2,976	\$524 million
2000 ³³	457	467	233	3,350	\$1.2 billion
2001 ³⁴	445	465	188	3,756	\$1.7 billion

28. CTR. FOR MEDICARE & MEDICAID SERVS., COMPREHENSIVE ERROR RATE TESTING (CERT) (2020), <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Improper-Payment-Measurement-Programs/Cert>. While the Biden administration has taken credit for this historically low error rate, the 2021 report was actually based on an analysis of claims submitted between July 2019 and June 2020, squarely during the Trump administration. See CTR. FOR MEDICARE & MEDICAID SERVS., 2021 MEDICARE FEE-FOR-SERVICE SUPPLEMENTAL IMPROPER PAYMENT DATA 1 (2021); CTR. FOR MEDICARE & MEDICAID SERVS., BIDEN-HARRIS ADMINISTRATION ANNOUNCES MEDICARE FEE-FOR-SERVICE ESTIMATED IMPROPER PAYMENTS DECLINE BY OVER \$20 BILLION SINCE 2014 (2021).

29. Of course, the reports only address the errors we can identify; there is no comparable method to measure activities that evade detection. See MALCOLM K. SPARROW, LICENSE TO STEAL: HOW FRAUD BLEEDS AMERICA’S HEALTH CARE SYSTEM 2 (2nd ed. 2000) (“What you see is not the problem. It’s what we don’t see that really does the damage.”).

30. *Health Care Fraud & Abuse Control Program Report*, OFF. INSPECTOR GEN., DEP’T HEALTH & HUM. SERVS., <https://oig.hhs.gov/reports-and-publications/hcfac/index.asp> (last visited Feb. 10, 2022).

31. DEP’T OF HEALTH & HUM. SERVS. & DEP’T JUST., HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FY 1998, at 1–2 (1999) [hereinafter 1998 HCFAC Rep.].

32. DEP’T OF HEALTH & HUM. SERVS. & DEP’T JUST., HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FY 1999, at 1, 8 (2000) [hereinafter 1999 HCFAC Rep.].

33. DEP’T OF HEALTH & HUM. SERVS. & DEP’T JUST., HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FY 2000, at 1 (2001) [hereinafter 2000 HCFAC Rep.].

34. DEP’T OF HEALTH & HUM. SERVS. & DEP’T JUST., HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FY 2001, at 1–2 (2002), [hereinafter 2001 HCFAC Rep.].

2002 ³⁵	361	480	221	3,448	\$1.8 billion
2003 ³⁶	362	437	231	3,275	\$1.8 billion
2004 ³⁷	1,002	459	868	3,293	\$605 million
2005 ³⁸	935	523	778	3,804	\$1.47 billion
2006 ³⁹	836	547	915	3,422	\$2.2 billion
2007 ⁴⁰	878	560	776	3,308	\$1.8 billion
2008 ⁴¹	957	588	843	3,129	\$1.0 billion
2009 ⁴²	1,014	583	886	2,556	\$1.63 billion
2010 ⁴³	1,116	726	942	3,340	\$2.5 billion
2011 ⁴⁴	1,100	743	977	2,662	\$2.4 billion

35. DEP’T OF HEALTH & HUM. SERVS. & DEP’T JUST., HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FY 2002, at 1–2 (2003) [hereinafter 2002 HCFAC Rep.].

36. DEP’T OF HEALTH & HUM. SERVS. & DEP’T JUST., HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FY 2003, at 1 (2004) [hereinafter 2003 HCFAC Rep.].

37. DEP’T OF HEALTH & HUM. SERVS. & DEP’T JUST., HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FY 2004, at 1–2, 11 (2005) [hereinafter 2004 HCFAC Rep.].

38. DEP’T OF HEALTH & HUM. SERVS. & DEP’T JUST., HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FY 2005, at 1, 19 (2006) [hereinafter 2005 HCFAC Rep.].

39. DEP’T OF HEALTH & HUM. SERVS. & DEP’T JUST., HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FY 2006, at 1, 25 (2007) [hereinafter 2006 HCFAC Rep.].

40. DEP’T OF HEALTH & HUM. SERVS. & DEP’T JUST., HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FY 2007, at 1, 25 (2008) [hereinafter 2007 HCFAC Rep.].

41. DEP’T OF HEALTH & HUM. SERVS. & DEP’T JUST., HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FY 2008, at 1, 23 (2009) [hereinafter 2008 HCFAC Rep.].

42. DEP’T OF HEALTH & HUM. SERVS. & DEP’T JUST., HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FY 2009, at 1, 32 (2010) [hereinafter 2009 HCFAC Rep.].

43. DEP’T OF HEALTH & HUM. SERVS. & DEP’T JUST., HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FY 2010, at 1 (2011) [hereinafter 2010 HCFAC Rep.].

44. DEP’T OF HEALTH & HUM. SERVS. & DEP’T JUST., HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FY 2011, at 1–2 (2012) [hereinafter 2011 HCFAC Rep.].

2012 ⁴⁵	1,131	826	885	3,131	\$3.0 billion
2013 ⁴⁶	1,013	718	1,083	3,214	\$2.6 billion
2014 ⁴⁷	924	734	782	4,017	\$2.3 billion
2015 ⁴⁸	983	613	808	4,112	\$1.9 billion
2016 ⁴⁹	975	658	930	3,635	\$2.5 billion
2017 ⁵⁰	967	639	948	3,244	\$2.4 billion
2018 ⁵¹	1,139	479	918	2,712	\$2.3 billion
2019 ⁵²	1,060	528	1,112	2,640	\$2.6 billion
2020 ⁵³	1,148	440	1,079	2,148	\$1.8 billion

As Table 1 indicates, the government’s fraud enforcement efforts have varied over time. Some of those variations track the enforcement policy changes described below, while others do not.⁵⁴ Apart from an early high point during the George W. Bush administration, for example, new criminal investigations reached a consistent high during the Obama administration, with its emphasis on criminal sanctions for fraud.⁵⁵ Yet the number of new criminal investigations

45. DEP’T OF HEALTH & HUM. SERVS. & DEP’T JUST., HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FY 2012, at 1–2 (2013) [hereinafter 2012 HCFAC Rep.].

46. DEP’T OF HEALTH & HUM. SERVS. & DEP’T JUST., HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FY 2013, at 1–2 (2014) [hereinafter 2013 HCFAC Rep.].

47. DEP’T OF HEALTH & HUM. SERVS. & DEP’T JUST., HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FY 2014, at 1–2 (2015) [hereinafter 2014 HCFAC Rep.].

48. DEP’T OF HEALTH & HUM. SERVS. & DEP’T JUST., HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FY 2015, at 1–2 (2016) hereinafter 2015 HCFAC Rep.].

49. DEP’T OF HEALTH & HUM. SERVS. & DEP’T JUST., HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FY 2016, at 1–2 (2017) [hereinafter 2016 HCFAC Rep.].

50. DEP’T OF HEALTH & HUM. SERVS. & DEP’T JUST., HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FY 2017, at 1 (2018) [hereinafter 2017 HCFAC Rep.].

51. DEP’T OF HEALTH & HUM. SERVS. & DEP’T JUST., HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FY 2018, at 3 (2019) [hereinafter 2018 HCFAC Rep.].

52. DEP’T OF HEALTH & HUM. SERVS. & DEP’T JUST., HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FY 2019, at 1 [hereinafter 2019 HCFAC Rep.].

53. DEP’T OF HEALTH & HUM. SERVS. & DEP’T JUST., HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FY 2020, at 1 [hereinafter 2020 HCFAC Rep.].

54. See *infra* Section II.B.

55. See *supra* tbl. 1 (new criminal investigations spiked in 2004, before decreasing and then remaining high between 2009 and 2016).

rose higher still during the Trump administration, even with a seemingly more defendant-friendly approach.⁵⁶ Despite the growing number of new *investigations*, however, the number of *convictions* followed a different path, increasing during the Obama administration to a high in 2012, only to begin a slow decline that would become a precipitous drop during President Donald Trump's time in office.⁵⁷

New civil investigations have also fluctuated, growing during the first half of President Barack Obama's time in office, only to drop and then rebound under President Trump.⁵⁸ With a few year-to-year exceptions, exclusions from the federal health care programs remained similar during the Bush and Obama administrations, with an increase in the latter part of the Obama administration that was reversed by President Trump.⁵⁹ And the total amount of judgments and settlements grew slowly during the Clinton and Bush administrations, reaching a high point during the Obama administration in 2012 before falling off; in both 2015 and 2020, recoveries reached a low more typical of the latter part of the Bush administration.⁶⁰

It is difficult to draw accurate conclusions from these numbers, however. Fraud cases are multi-year undertakings, often requiring years of background investigation before a complaint is filed, followed by attempts at negotiation and then, perhaps, by trial and subsequent appeals.⁶¹ The infamous case of *United States v. Krizek*, for example, began with an audit of billing codes used by District of Columbia psychiatrists in 1988 and the execution of a subpoena by the HHS Office of the Inspector General (OIG) in 1989, followed by a request for records in 1991, a demand letter issued in 1992, a year of failed negotiations, a three-week bench trial in 1994, multiple appeals, and a final judgment paid in 2002—a period that began during the first Bush administration, spanned President Bill Clinton's entire time in office, and ended only after the second Bush was elected President.⁶²

Focusing too closely on annual recoveries similarly paints an incomplete picture of fraud enforcement. It is impossible to judge the effectiveness of enforcement efforts by looking to recoveries in any single year, chiefly because

56. See *supra* tbl. 1 (new criminal investigations rose after 2017).

57. See *supra* tbl. 1 (criminal convictions rose between 2009 and 2012 before falling).

58. See *supra* tbl. 1 (new civil investigations rose between 2009 and 2013, then dropped and rebounded in 2016).

59. See *supra* tbl. 1 (exclusions remained stable between 2001 and 2011, grew between 2012 and 2016, and dropped after 2017).

60. See *supra* tbl. 1 (total judgments grew steadily until 2012 before falling off).

61. 2020 HCFAC Rep., *supra* note 53, at 92.

62. See Joan H. Krause & Timothy L. Greaney, *United States v. Krizek: Rough Justice Under the Civil False Claims Act*, in *HEALTH LAW AND BIOETHICS: CASES IN CONTEXT* 187, 188–96 (Sandra Johnson et al. eds., 2009) (describing the tortured history of *Krizek* litigation).

those numbers can be skewed by a few large settlements.⁶³ The record three billion dollars in judgments and settlements in 2012, for example, was driven by one massive settlement with GlaxoSmithKline, resolving both criminal and civil liability related to the company's drugs.⁶⁴ Moreover, because large settlements may be negotiated in one year but collected over subsequent years, settlements and judgments in one fiscal year usually do not equal recoveries in that same year.⁶⁵ Although the government won or negotiated only \$1.8 billion in health care fraud judgments and settlements in fiscal year (FY) 2020, for example, it actually collected almost \$3.1 billion due to cases resolved in prior years.⁶⁶

It is too early to assess the results of fraud enforcement under the Biden administration. Federal FY 2020, the latest year for which full data is available, ran from October 1, 2019, through September 30, 2020, yet President Biden was not sworn in until January 2021.⁶⁷ The 2020 numbers, then, are the numbers for the final year of the Trump administration, just as the numbers for 2016 reflected the end of the Obama administration.⁶⁸ Moreover, it may take several years for DOJ staff to complete their work on investigations already in progress when the presidential administration changes. For now, it remains too early to know the financial impact of the Biden administration on health care fraud enforcement, although there have been indications that some policies will indeed change.⁶⁹

C. Rhetoric and Money

Whether or not health care fraud is at the top of the presidential agenda is often signaled not only by rhetoric, but also by whether that rhetoric is supported by budget requests. When former Attorney General Janet Reno designated health care fraud as the DOJ's "number two" priority in 1994, second only to violent crime, the Clinton administration signaled that health care fraud would

63. See 2012 HCFAC Rep., *supra* note 45, at 1, 19.

64. *Id.*; *GlaxoSmithKline to Plead Guilty and Pay \$3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data*, U.S. DEP'T JUST. (July 2, 2012), <https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report>.

65. 2020 HCFAC Rep., *supra* note 53, at 1.

66. *Id.*

67. *Budget of the U.S. Government*, USA.GOV, <https://www.usa.gov/budget> (last visited Feb. 16, 2022).

68. See 2016 HCFAC Rep., *supra* note 49; 2020 HCFAC Rep., *supra* note 53.

69. Michael D. Granston, Deputy Assistant Att'y Gen., Dep't of Just., Remarks at the ABA Civil False Claims Act and Qui Tam Enforcement Institute (Dec. 2, 2020), <https://www.justice.gov/opa/speech/remarks-deputy-assistant-attorney-general-michael-d-granston-aba-civil-false-claims-act>. As an early indicator of the Biden administration's work, the DOJ announced in February 2022 that the FY 2021 FCA numbers exceeded \$5.6 billion. Off. of Pub. Affs., *Justice Department's False Claims Act Settlements and Judgments Exceed \$5.6 Billion in Fiscal Year 2021*, U.S. DEP'T JUST. (Feb. 1, 2022), <https://www.justice.gov/opa/pr/justice-department-s-false-claims-act-settlements-and-judgments-exceed-56-billion-fiscal-year>.

be a national priority.⁷⁰ That rhetoric was backed up by the legislative effort that resulted in the Health Insurance Portability and Accountability Act (HIPAA), which not only defined a series of new health care crimes, but also created the Health Care Fraud and Abuse Control (HCFAC) Program to oversee federal enforcement efforts.⁷¹ Some portion of the anti-fraud budget is set by statute: under HIPAA, money recovered from health care fraud enforcement efforts is available for appropriation back to the Health Care Fraud and Abuse Control Account (Control Account), which specifically funds fraud enforcement activity by the DOJ and HHS.⁷² Appropriations to the Control Account are set by the Secretary of HHS and the Attorney General, who jointly certify the amounts necessary to fund anti-fraud programs each year within broad ranges set by Congress.⁷³

The President remains free to request additional anti-fraud resources if that matches other priorities. President Obama's 2010 budget proposal, for example, requested fifty percent more in increased anti-fraud funding compared to 2009, which he estimated to save \$2.7 billion over five years—a request occurring simultaneously with the effort to expand health insurance coverage under the Patient Protection and Affordable Care Act (ACA).⁷⁴ The Obama administration was not shy about making that link explicit; as a 2009 *60 Minutes* segment noted, “President Obama says rising costs are driving huge federal budget deficits that imperil our future, and that there is enough waste and fraud in the system to pay for health care reform if it was eliminated.”⁷⁵

During the initial months of the Biden presidency, health care fraud did not appear to be a rhetorical or budgetary priority.⁷⁶ Despite proposing a 23.4% increase in the HHS budget for FY 2022 and offering reforms that ranged from rebuilding the public health infrastructure to improving Medicare and Medicaid coverage and lowering prescription drug costs, President Biden's budget

70. See JANET RENO, DEP'T JUST., 1994 ANN. REP. OF THE ATT'Y GEN. (in Chapter I, Health Care Fraud).

71. 42 U.S.C. § 1320a-7c.

72. Health Insurance Portability and Accountability Act, Pub. L. No. 104-191, 110 Stat. 1936, 1992, 1994 (1996); § 1395i(k)(3) (describing appropriations to the Control Account); Joan H. Krause, *A Patient-Centered Approach to Health Care Fraud Recovery*, 96 J. CRIM. L. & CRIMINOLOGY 579, 596 (2006) (describing HIPAA funding mechanism).

73. § 1395i(k)(3)(A)(i).

74. See Off. Pub. Affs., *Attorney General Holder and HHS Secretary Sebelius Announce New Interagency Health Care Fraud Prevention & Enforcement Action Team*, U.S. DEP'T JUST. <https://www.justice.gov/opa/pr/attorney-general-holder-and-hhs-secretary-sebelius-announce-new-interagency-health-care-fraud> (updated Oct. 8, 2014).

75. *Medicare Fraud: A \$60 Billion Crime*, 60 MINUTES (Oct. 25, 2009, 1:42 PM), <https://www.cbsnews.com/news/medicare-fraud-a-60-billion-crime-23-10-2009/>.

76. See OFF. OF MGMT. & BUDGET, OFF. OF THE PRESIDENT, BUDGET OF THE UNITED STATES GOVERNMENT, FISCAL YEAR 2022 (2021) (describing enforcement priorities).

proposal did not single out health care fraud and abuse for additional funding.⁷⁷ Indeed, HHS requested \$2.4 million *less* in funding for Medicare and Medicaid oversight for FY 2022 than in the FY 2021 budget,⁷⁸ and the DOJ requested \$2.2 million less.⁷⁹

D. Changes in Enforcement Policy

While rhetoric and budget requests function as public markers of a commitment to preventing fraud, the operational effect of changing priorities is achieved by more granular evolution of the documents that guide federal prosecutors. Because of significant overlap in the conduct covered by civil, administrative, and criminal fraud laws, the choice of whether a case will be pursued as a criminal or civil matter, or perhaps declined altogether, is often left to prosecutorial discretion.⁸⁰ Those choices are influenced by “prosecution guidelines, enforcement initiatives, and both formal and informal interagency understandings regarding which agency has primary jurisdiction in different types of cases—all of which are subject to change” depending on the administration.⁸¹ Those changes have been evident not only historically, but also in recent actions by President Biden to undo some of the changes made by his predecessor.⁸²

As demonstrated by Table 1, while civil fraud prosecutions were prominent for much of the Bush administration, the early years of the Obama administration saw a greater focus on criminal investigations.⁸³ That change was also evident in a 2014 announcement that the DOJ Civil Division would share all new private FCA complaints with the DOJ Criminal Division as soon as they were filed, significantly increasing the chances that *qui tam* suits would be accompanied by parallel criminal proceedings.⁸⁴ When President Trump took office, the guidance pivoted, with the administration adopting far more defendant-friendly policies. A memorandum issued in January 2018 by Michael D. Granston, the Director of the Fraud Section of the DOJ’s Commercial Litigation Branch, encouraged the dismissal of many private FCA cases based

77. *Id.* at 17, 24, 57.

78. OFF. OF INSPECTOR GEN., U.S. DEP’T OF HEALTH & HUM. SERVS., FISCAL YEAR 2022: JUSTIFICATION OF ESTIMATES FOR CONGRESS 16 (2022).

79. DEP’T JUST., FISCAL YEAR 2022 BUDGET REQUEST AT A GLANCE 17, 24, 57 (2021) (explaining the difference as “due to changes in CARES Act related mandatory sequester suspension.”).

80. Krause, *supra* note 5, at 358 (describing choice of enforcement pathways).

81. *Id.*

82. Exec. Order No. 13,992, 86 Fed. Reg. 7049 (Jan. 20, 2021) (“Revocation of Certain Executive Orders Concerning Federal Regulation”).

83. *See supra* tbl. 1 (showing an increase in the number of criminal investigations during the first years of the Obama administration).

84. Leslie R. Caldwell, Assistant Att’y Gen., Crim. Div., Remarks at the Taxpayers Against Fraud Education Fund Conference (Sept. 17, 2014).

on factors that could include the need to curb “meritless” *qui tam* suits, prevent “parasitic or opportunistic” *qui tam* suits, avoid interference with agency policies, control litigation brought on the government’s behalf, safeguard classified or national security information, and preserve government resources.⁸⁵

These changing enforcement policies may have very practical effects on ongoing litigation. Pharmaceutical companies Eli Lilly and Bayer, for example, became embroiled in litigation involving the Trump administration’s commitment to dismiss *qui tam* suits.⁸⁶ In September 2019, a federal district court judge upheld the government’s dismissal of a suit brought by relator Health Choice Alliance alleging the companies had knowingly induced the submission of false claims by violating the Anti-Kickback Statute with regard to various marketing and reimbursement activities.⁸⁷ The government’s decision was based on factors echoing the Granston Memorandum: questions regarding the sufficiency of the evidence and legal support for the alleged theories of fraud, the costs to the government of maintaining the action, potential interference with the policy interests of the federal health care programs, and concerns over the “investigative methods employed by” the relator.⁸⁸ The Fifth Circuit affirmed.⁸⁹

The Trump administration also mounted a multifaceted attack on the practice of using noncompliance with informal agency guidance documents as the basis for prosecution.⁹⁰ In a November 2017 memorandum on the “Prohibition on Improper Guidance Documents,” then-Attorney General Jeff Sessions stressed the importance of using notice-and-comment rulemaking to establish agency policy and directed the DOJ not to use “guidance [to] create binding standards by which the Department will determine compliance with existing regulatory or statutory requirements.”⁹¹ In January 2018, then-Associate Attorney General Rachel Brand clarified that the DOJ “may not use its enforcement authority to effectively convert guidance documents into binding rules,” and that prosecutors “may not use noncompliance with guidance documents as a basis for proving violations of applicable law” in civil cases.⁹²

85. See Memorandum from Michael D. Granston, Dir., Com. Litig. Branch, Fraud Section, on Factors for Evaluating Dismissal Pursuant to 31 U.S.C. 3730(c)(2)(A), at 3–6 (Jan. 10, 2018).

86. Health Choice All. LLC *ex rel.* United States v. Eli Lilly & Co., No. 5:17-CV-00126, 2019 WL 4727422, at *2 (E.D. Tex. Sept. 27, 2019); *In re* Baycol Prods. Litig., 870 F.3d 960, 961 (8th Cir. 2017).

87. *Health Choice All.*, 2019 WL 4727422, at *1, *8.

88. United States *ex rel.* Health Choice All. v. Eli Lilly, 4 F.4th 255, 260 (5th Cir. 2021).

89. *Id.* at 269.

90. Memorandum from the Att’y Gen. to All Components on Prohibition on Improper Guidance Documents (Nov. 16, 2017).

91. *Id.*

92. Memorandum from Rachel Brand, Associate Att’y Gen. to Heads of Civil Litigating Components and United States Attorney on Limiting Use of Agency Guidance Documents in Affirmative Civil Enforcement Cases (Jan. 25, 2018).

In October 2019, President Trump doubled down on the requirement of official rulemaking, issuing an Executive Order on “Promoting the Rule of Law through Improved Agency Guidance Documents.”⁹³

Given the key role of guidance documents in many FCA cases, particularly those involving Medicare and Medicaid rules, the new policy left many uncertain about future enforcement.⁹⁴ President Biden did not waste any time addressing the issue: he revoked the Executive Order, among others, on his first day in office.⁹⁵ In July 2021, Attorney General Merrick Garland rescinded both the Sessions and Brand memoranda, reiterating the importance of informal agency guidance and permitting the DOJ to use such guidance in “any appropriate and lawful circumstances, including when a guidance document may be entitled to deference or otherwise carry persuasive weight with respect to the meaning of the applicable legal requirements.”⁹⁶

A similar evolution has occurred in the DOJ’s approach to prosecuting corporate fraud, an area of major concern given the number of corporate entities in the health care market. During the Clinton administration, the DOJ issued a memorandum on “Federal Prosecution of Corporations” setting forth the factors that would guide the decision of whether to bring federal charges against a corporation, including the corporation’s willingness to waive the attorney-client and work product privileges in order to demonstrate cooperation.⁹⁷ In the wake of the Enron and WorldCom scandals, the Bush administration revised the guidance to include consideration of whether the responsible individuals could be prosecuted, but appeared to back off from the demand that corporations waive the privileges.⁹⁸ In 2015, the Obama DOJ released the “Yates Memorandum,” vowing to pursue action against both corporations and any individuals involved

93. Exec. Order No. 13,891, 84 Fed. Reg. 55,235 (Oct. 9, 2019).

94. One law firm explained the effect of the policy on the Medicare Claims Processing Manual, noting that “the DOJ could no longer actively enforce the instruction manual that every provider in America relied upon for decades when billing Medicare (or other similar agency manuals). It could use these documents to evince scienter (i.e., knowledge that they were breaking the rules), but what good was that if the rules were not binding?” Jason Marcus, *Attorney General Merrick Garland Rescinds the Infamous Brand Memo*, BRACKER & MARCUS LLC (Sept. 10, 2021), <https://www.fcacounsel.com/blog/attorney-general-merrick-garland-rescinds-infamous-brand-memo/>.

95. Exec. Order No. 13,992, *supra* note 82.

96. Memorandum from Merrick Garland, Att’y Gen. to Heads of All Department Components on Issuance and Use of Guidance Documents by the Department of Justice (July 1, 2021); *see also* *Kisor v. Wilkie*, 139 S. Ct. 2400, 2420 (2019) (noting an agency guidance document by “itself never forms ‘the basis for an enforcement action’ because” such documents cannot “impose any ‘legally binding requirements’ on private parties”).

97. Memorandum from Eric H. Holder, Jr., Deputy Att’y Gen. to All Component Heads and U.S. Att’ys on Bringing Criminal Charges Against Corporations (June 16, 1999).

98. *See* Gideon Mark, *The Yates Memorandum*, 51 U.C. DAVIS L. REV. 1589, 1598 (2018) (discussing the memoranda).

in the wrongdoing, and making clear that in order to be eligible for cooperation credit, the company must identify all the individuals who were involved in or responsible for the misconduct.⁹⁹ Under President Trump, however, Deputy Attorney General Rod J. Rosenstein noted that while “the notion that companies should be required to locate and report to the government every person involved in alleged misconduct in any way, regardless of their role, may sound reasonable,” it was not feasible in practice; by 2018, the DOJ had pulled back to require the identification only of “individuals substantially involved in or responsible for the misconduct” at issue.¹⁰⁰

After initial silence, the Biden administration waded into the debate in late October 2021, reviving and reinvigorating the approach originally taken in the Yates memorandum.¹⁰¹ In a keynote address at the American Bar Association’s National Institute on White Collar Crime, Deputy Attorney General Lisa Monaco announced that it was “unambiguously this department’s first priority in corporate criminal matters to prosecute the individuals who commit and profit from corporate malfeasance.”¹⁰² The policy reinstated the requirement that a corporation identify *all* individuals involved in the misconduct and provide the DOJ with all relevant non-privileged information about those individuals.¹⁰³ The DOJ also made clear that it would take into account the full range of prior misconduct by the company—not just similar types of misbehavior—in determining the proper disposition of an investigation.¹⁰⁴ Repeated wrongdoing by corporations, even if spread among different areas of responsibility, will thus play a greater role than in the past.¹⁰⁵ Although some of these changes may appear to be only ones of degree, overall they do signal a different approach to general corporate fraud issues.

III. FRAUD CHALLENGES FACING THE BIDEN ADMINISTRATION

While the enthusiasm for engaging in anti-fraud efforts varies by administration, it really is a question of how, rather than if, health care fraud will be a significant part of the federal enforcement agenda. Where will the Biden administration focus its health care fraud efforts? Although it may be too early

99. Memorandum from Sally Quillian Yates, Deputy Att’y Gen. to Assistant Att’y Gens. of the Antitrust, Civil, Crim., Env’t and Natural Resources, Nat’l Sec., and Tax Div.; Dir. of the Fed. Bureau of Investigation; Dir. of the Exec. Off. for U.S. Trustees; and All U.S. Att’ys on Individual Accountability for Corporate Wrongdoing (Sept. 9, 2015).

100. Att’y Gen. Rod J. Rosenstein, Remarks at the American Conference Institute’s 35th International Conference on the Foreign Corrupt Practices Act (Nov. 29, 2018).

101. Deputy Att’y Gen. Lisa O. Monaco, ABA’s 36th National Institute on White Collar Crime (Oct. 28, 2021).

102. *Id.*

103. *Id.*

104. *Id.*

105. *Id.*

to tell, three areas are likely to demand continued attention: (1) the COVID-19 pandemic, including not only the disbursement of large amounts of federal funding, but also the loosening of traditional limits on Medicare reimbursement for telehealth; (2) the ongoing transition from volume- to value-based forms of payment, and the varying forms of fraud incentivized by each; and (3) the continuing vitality of more typical forms of fraud, particularly in the pharmaceutical industry.

A. *Pandemic-Related Fraud*

The single biggest health care fraud concern facing President Biden is, of course, the COVID-19 pandemic. The pandemic has disrupted life as we knew it in ways far too numerous to list here.¹⁰⁶ For the purposes of health care fraud, however, two of the government's COVID-19 initiatives have been key. First, the government has allocated large sums of money to the health care industry, both as a general economic stimulus and to provide funding for COVID-related care.¹⁰⁷ To the extent fraud follows funding, we can anticipate a growing number of enforcement efforts aimed at providers who fail to use the funding for its intended purposes.¹⁰⁸ Second, to ease disruptions in traditional in-person care, the government has waived many existing limitations, such as permitting the broader use of telehealth services and suspending some of the traditional fraud and abuse authorities during the public health emergency.¹⁰⁹ Both efforts are likely to create opportunities for fraud to flourish.

The pandemic certainly has created opportunities for basic types of fraud schemes aimed at consumers and other purchasers. When vaccines were initially in short supply, unscrupulous individuals set up web sites purporting to sell the (free) shots.¹¹⁰ When personal protective equipment was scarce, fraudsters created schemes to sell counterfeit or nonexistent equipment to health care facilities.¹¹¹ Efforts to prey on a fearful public by marketing false COVID

106. Abid Haleem & Mohd Javaid, *Effects of COVID-19 Pandemic in Daily Life*, 10 CURRENT MED. RSCH. PRAC. 78, 78 (2020).

107. *See, e.g.*, CARES Act, 134 Stat. 367.

108. *See, e.g.*, Allie Reed, *Doctors Asked to Repay \$100 Million in Covid Aid Absent Reports*, BLOOMBERG L. (Mar. 30, 2022, 3:07 PM), <https://news.bloomberglaw.com/health-law-and-business/doctors-asked-to-repay-100-million-in-covid-aid-absent-reports> (describing efforts to recoup money from health care providers who received first round of PRG funding).

109. *Medicare Telemedicine Health Care Provider Fact Sheet*, *supra* note 4.

110. *See* Henderson, *supra* note 3.

111. *See, e.g.*, *Georgia Man Arrested for Attempting to Defraud the Department of Veterans Affairs in a Multimillion-Dollar COVID-19 Scam*, U.S. DEP'T JUST. (Apr. 10, 2020), <https://www.justice.gov/usao-dc/pr/georgia-man-arrested-attempting-defraud-department-veterans-affairs-multimillion-dollar> (alleged attempt to sell nonexistent respirator masks in exchange for large upfront payment).

“cures” flourished.¹¹² The influx of large amounts of funding, however, has been a literal game-changer for fraud schemes.

The Coronavirus Aid, Relief, and Economic Security Act (CARES Act) and subsequent relief legislation allocated more than \$175 billion in provider relief funds to hospitals and front-line health care providers, to be disbursed by the Health Resources and Services Administration (HRSA).¹¹³ Those funds, however, come with a caveat: providers must agree to use the money only for specified purposes and must agree to abide by the program’s terms and conditions.¹¹⁴ Not surprisingly, given the amount of money at stake, there is concern that some providers have accepted those funds but failed to comply with those conditions, or found ways to bill the program unnecessarily—the exact types of schemes actionable under the FCA by both federal prosecutors and *qui tam* relators.¹¹⁵ The 2020 HCFAC Report identified four types of COVID-related fraud investigated by the government: additional or unnecessary services, such as offering COVID-19 tests to Medicare beneficiaries in return for their personal information; unnecessary laboratory testing paired with COVID-19 tests, such as allergy or genetic testing; falsely representing to insurers the provision of COVID-19 tests and treatment; and fraudulently obtaining relief funds, including filing false claims and applications.¹¹⁶

The federal government has responded to these threats by prioritizing COVID-related fraud enforcement.¹¹⁷ One of the first prosecutions was a May 2020 case charging a Georgia woman with conspiracy to defraud Medicare by paying kickbacks in exchange for referring Medicare beneficiaries for unnecessary genetic screening and COVID-19 tests.¹¹⁸ In December 2020, HHS announced the creation of a False Claims Act Working Group in partnership with the DOJ and OIG, citing the rising need for FCA investigations in light of the “unprecedented levels of taxpayer support” offered through COVID-19 relief.¹¹⁹ The Biden administration has embraced these enforcement efforts,

112. Meagan Flynn, *Small-Time Actor Peddled Fake Coronavirus Cure to Millions Online, Feds Charge in First Covid-19 Prosecution*, WASH. POST (Mar. 26, 2020), <https://www.washingtonpost.com/nation/2020/03/26/fake-coronavirus-cure-fraud>.

113. *General Distributions*, HEALTH RES. & SERVS. ADMIN., <https://www.hrsa.gov/provider-relief/data/general-distribution> (last visited Feb. 19, 2022).

114. *Terms and Conditions*, HEALTH RES. & SERVS. ADMIN., <https://www.hrsa.gov/provider-relief/past-payments/terms-conditions> (last visited Feb. 19, 2021).

115. 2020 HCFAC Rep., *supra* note 53, at 13.

116. *Id.*

117. *Id.*

118. *Georgia Woman Arrested for Role in Scheme to Defraud Health Care Benefit Programs Related to Cancer Genetic Testing and COVID-19 Testing*, U.S. DEP’T JUST. (May 15, 2020), <https://www.justice.gov/opa/pr/georgia-woman-arrested-role-scheme-defraud-health-care-benefit-programs-related-cancer>.

119. *HHS Announces False Claims Act Working Group to Enhance Efforts to Combat Fraud and Focus Resources on Bad Actors*, U.S. DEP’T HEALTH & HUM. SERVS. (Dec. 4, 2020),

announcing a new DOJ COVID-19 Fraud Enforcement Task Force and publicly announcing the filing of criminal charges against fourteen defendants nationwide for pandemic-related fraud schemes in May 2021.¹²⁰ Those efforts are likely to continue, and indeed to increase. In his first State of the Union address in March of 2022, President Biden announced plans to focus on “major targets of pandemic fraud, such as those committing large-scale identity theft,” and called on Congress to provide additional resources and enact stricter penalties.¹²¹ Soon after, the DOJ announced that the agency had taken enforcement action against more than eight billion dollars in alleged pandemic relief fraud and appointed a new Director for COVID-19 Fraud Enforcement.¹²²

Another type of fraud exposure stems from the government’s efforts to remove barriers to patient care created by the pandemic, particularly the limitations imposed by restrictions on physician self-referral under the Stark Law.¹²³ In March 2020, CMS issued a “blanket waiver” of sanctions under the Stark Law relating to COVID-19, intending to provide flexibility to providers with regard to their referral and compensation arrangements; in early April, OIG issued a parallel statement confirming that the agency would not impose Anti-Kickback sanctions for activities covered by the Stark waivers.¹²⁴ Those waivers are time-limited, expiring when the Secretary of HHS declares an end to the

<https://public3.pagefreezer.com/browse/HHS%20%E2%80%93%20About%20News/20-01-2021T12:29/https://www.hhs.gov/about/news/2020/12/04/hhs-announces-false-claims-act-working-group-enhance-efforts-combat-fraud-and-focus-resources-bad-actors.html>.

120. *DOJ Announces Coordinated Law Enforcement Action to Combat Health Care Fraud Related to COVID-19*, U.S. DEP’T JUST. (May 26, 2021), <https://www.justice.gov/opa/pr/doj-announces-coordinated-law-enforcement-action-combat-health-care-fraud-related-covid-19>;

Attorney General Announces Task Force to Combat COVID-19 Fraud, U.S. DEP’T JUST. (May 17, 2021), <https://www.justice.gov/opa/pr/attorney-general-announces-task-force-combat-covid-19-fraud>.

121. *Fact Sheet: President Biden to Announce New Steps to Combat Criminal Fraud and Identity Theft in Pandemic Relief Programs*, WHITE HOUSE (Mar. 1, 2022), <https://www.whitehouse.gov/briefing-room/statements-releases/2022/03/01/fact-sheet-president-biden-to-announce-new-steps-to-combat-criminal-fraud-and-identity-theft-in-pandemic-relief-programs/>.

122. *Justice Department Announces Director for COVID-19 Fraud Enforcement*, U.S. DEP’T JUST. (Mar. 10, 2022), <https://www.justice.gov/opa/pr/justice-department-announces-director-covid-19-fraud-enforcement>.

123. *See* CTRS. FOR MEDICARE & MEDICAID SERVS., BLANKET WAIVERS OF SECTION 1877(G) OF THE SOCIAL SECURITY ACT DUE TO DECLARATION OF COVID-19 OUTBREAK IN THE UNITED STATES AS A NATIONAL EMERGENCY (Mar. 2020), <https://www.cms.gov/files/document/covid-19-blanket-waivers-section-1877g.pdf> (waiving sanctions for certain violations of Stark Law prohibitions on physician self-referral during the COVID-19 pandemic).

124. *Id.* at 1, 3; OFF. OF INSPECTOR GEN., DEP’T OF HEALTH & HUM. SERVS., OIG POLICY STATEMENT REGARDING APPLICATION OF CERTAIN ADMINISTRATIVE ENFORCEMENT AUTHORITIES DUE TO DECLARATION OF CORONAVIRUS DISEASE 2019 (COVID-19) OUTBREAK IN THE UNITED STATES AS A NATIONAL EMERGENCY (Apr. 3, 2020), <https://oig.hhs.gov/coronavirus/OIG-Policy-Statement-4.3.20.pdf>.

public health emergency.¹²⁵ While at present that date remains to be determined, whenever it arrives, providers will have to untangle a number of arrangements that otherwise may be in violation of the law. Moreover, to the extent the waivers apply only for certain COVID-related purposes, we can anticipate investigations against providers who intertwine their COVID- and non-COVID-related activities or flatly mischaracterize their activities in an effort to take advantage of the waivers.

The government also offered pandemic-related flexibility with regard to telehealth services.¹²⁶ COVID-related disruptions to in-person care, whether due to shelter-in-place requirements, lack of adequate facility space, or simple precautionary measures, drove many providers to offer services remotely through telephone and video chats.¹²⁷ Historically, Medicare offered little coverage of telehealth services, limiting them mostly to rural areas.¹²⁸ In March 2020, however, CMS issued a waiver permitting Medicare to pay for medical visits provided by telehealth nationwide, with no geographical restrictions; telehealth coverage recently was extended through 2023.¹²⁹ Not surprisingly, the result has been a significant increase in the number of telehealth visits—and in potential telehealth fraud.¹³⁰

Even before the pandemic, telehealth services were on the Trump administration's fraud radar.¹³¹ In September 2020, the DOJ announced the largest health care fraud enforcement action in history, accusing 345 defendants of fraudulently billing more than six billion dollars—\$4.5 billion of which was attributed to telemedicine schemes involving eighty-six defendants across the

125. *See id.* at 1 (noting that a public health emergency is a prerequisite for the waiver, so the waiver will end when the Secretary declares the public health emergency is over).

126. *See, e.g., CMS Physician Payment Rule Promotes Greater Access to Telehealth Services, Diabetes Prevention Programs*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Nov. 2, 2021), <https://www.cms.gov/newsroom/press-releases/cms-physician-payment-rule-promotes-greater-access-telehealth-services-diabetes-prevention-programs> (noting an expansion of telehealth services for behavioral health services).

127. LOK WONG SAMSON ET AL., OFF. OF THE ASSISTANT SEC'Y FOR PLAN. & EVALUATION, MEDICARE BENEFICIARIES' USE OF TELEHEALTH IN 2020: TRENDS BY BENEFICIARY CHARACTERISTICS AND LOCATION (Dec. 3, 2021), <https://aspe.hhs.gov/reports/medicare-beneficiaries-use-telehealth-2020>.

128. *Medicare Telemedicine Health Care Provider Fact Sheet*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Mar. 17, 2020), <https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet>.

129. *Id.*; *CMS Physician Payment Rule Promotes Greater Access to Telehealth Services*, *supra* note 126.

130. SAMSON ET AL., *supra* note 127, at 4 (finding that Medicare FFS telehealth visits increased sixty-three-fold, from 840,000 in 2019 to almost 52.7 million in 2020).

131. *National Health Care Fraud and Opioid Takedown Results in Charges Against 345 Defendants Responsible for More than \$6 Billion in Alleged Fraud Losses*, U.S. DEP'T JUST. (Sept. 30, 2020), <https://www.justice.gov/criminal-fraud/hcf-2020-takedown/press-release>.

country.¹³² The allegations, which were based on pre-pandemic activities, largely involved schemes by telemarketing companies that paid medical personnel to order unnecessary equipment, testing, and medications with little patient contact, then sold those orders to entities such as pharmacies and medical equipment companies that would submit fraudulent bills for those items to Medicare.¹³³

The Biden administration, however, has taken pains to distinguish these “telefraud” schemes from the types of telehealth fraud likely to arise due to COVID-19 flexibility.¹³⁴ Unlike schemes designed to obtain payment for ancillary items and services such as tests or medical equipment, COVID-related telehealth fraud is likely to involve the types of fraud more characteristic of in-person care: upcoding, providing unnecessary services, or billing for services that did not take place.¹³⁵ The industry certainly is aware of the increased scrutiny.¹³⁶ As one health care attorney said, “[t]o the extent that there’s fraud in telehealth and telemedicine, it’s no different from in-person care, and no more frequent. And in some ways telehealth is better from a fraud perspective because of the electronic trail it leaves behind.”¹³⁷ This additional electronic trail may make it easier for government investigators to trace potential instances of fraud. The Biden administration clearly has embraced fraud in telehealth expansion as an enforcement priority, announcing criminal charges in September 2021 against nine defendants for, among other things, exploiting the provisions of the telehealth waivers.¹³⁸ These efforts are likely to become more common over the next few years.

132. *Id.*

133. *Id.*

134. See Christi A. Grimm, *Principal Deputy Inspector General Grimm on Telehealth*, OFF. INSPECTOR GEN., U.S. DEP’T OF HEALTH & HUM. SERVS. (Feb. 26, 2021), <https://oig.hhs.gov/coronavirus/letter-grimm-02262021.asp> (clarifying differences).

135. Matthew Sitton, *Telemedicine Fraud During the Pandemic and Beyond*, AM. HEALTH L. ASS’N (Jan. 12, 2021), <https://www.americanhealthlaw.org/content-library/publications/briefings/2b1ccdee-f1f1-4502-910d-861e6b6195bd/telemedicine-fraud-during-the-pandemic-and-beyond>.

136. See Christopher Brown, *Federal Audits of Telehealth to Shape Its Post-Pandemic Future*, BLOOMBERG L. (Sept. 8, 2021, 4:35 AM), <https://news.bloomberglaw.com/health-law-and-business/federal-audits-of-telehealth-to-shape-its-post-pandemic-future> (quoting Krista Drobac, Executive Director of the Alliance for Connected Care).

137. *Id.*

138. *National Health Care Fraud Enforcement Action Results in Charges Involving Over \$1.4 Billion in Alleged Losses*, U.S. DEP’T. OF JUST. (Sept. 17, 2021), <https://www.justice.gov/opa/pr/national-health-care-fraud-enforcement-action-results-charges-involving-over-14-billion>. Notably, DOJ also brought charges against forty-three defendants for submitting over \$1.1 billion in fraudulent claims in more typical “telefraud” schemes. *Id.*

B. Transition from Volume- to Value-Based Payment

President Biden assumed office during a time of transition in federal health care program reimbursement. Historically, health care in the United States—including care rendered through the federal health care programs—has been reimbursed using a “fee-for-service” (FFS) system in which providers are paid for each separate service performed for a patient.¹³⁹ Not only does FFS encourage overtreatment, inefficiency, and the fragmentation of care, it also creates opportunity for fraud: the more care provided (or at least billed), the more payment will be made, regardless of whether that care is necessary or high quality.¹⁴⁰ For a number of years, both private and public payers tried to use “managed care” strategies to control health care costs, imposing both risk-based incentives and administrative controls to reduce unnecessary and nonbeneficial care.¹⁴¹ To the extent these strategies reduced costs, however, they did so in part by limiting access to expensive treatments and restricting patients to limited networks of providers.¹⁴² While these strategies blunted incentives to provide excessive care, they arguably went too far in the opposite direction, potentially incentivizing providers to offer less treatment than needed or to prefer patients less likely to need expensive care.¹⁴³ The result left both patients and health care providers dissatisfied.¹⁴⁴

One of the key aspects of the ACA was to transform Medicare reimbursement to reward providers for the *value* rather than the volume of services—not simply by measuring costs alone, as managed care tried to do, but by rewarding providers for offering higher-quality, more efficient, and better-coordinated services.¹⁴⁵ Starting in 2013, hospitals became eligible for value-based incentive payments if they met performance standards for the treatment of

139. Andrea R. Cunha et al., *From Payment to Volume to Payment for Value*, AM. HEALTH L. CONNECTIONS (Nov. 1, 2021), <https://www.americanhealthlaw.org/content-library/connections-magazine/article/5ce6d888-da86-4f76-b130-6b07fed77eb0/from-payment-for-volume-to-payment-for-value>.

140. See Joan H. Krause, *Integration, Fragmentation, and Human Nature: The Role of the Fraud and Abuse Laws in a Changing Healthcare System*, in THE OXFORD HANDBOOK OF U.S. HEALTH LAW 852, 853 (I. Glenn Cohen et al. eds., 2017).

141. *Id.* at 864, 869.

142. See Michael E. Porter & Robert S. Kaplan, *How to Pay for Health Care*, HARV. BUS. REV., Jul.–Aug. 2016, at 88, 92 (explaining how capitation, a managed care strategy, “restrict[s] patient choice and inhibit[s] provider competition”).

143. *Id.*

144. See Krause, *supra* note 140, at 869 (noting that managed care strategies “appeared to be designed primarily to deny care” and resulted in “[p]hysician and patient dissatisfaction” that led “to a managed care backlash”).

145. Porter & Kaplan, *supra* note 142, at 92; 42 U.S.C. § 1395w-4(p) (value-based payment modifier for physicians); § 1395ww(o) (hospital value-based purchasing program); Medicare Access and CHIP Reauthorization Act of 2015, Pub. L. No. 114-10, § 101(c), 129 Stat. 87, 92 (2015) (changing physician payment).

specified conditions and procedures, such as acute myocardial infarction, heart failure, and pneumonia.¹⁴⁶ A similar value-based modifier for physician services went into effect in 2015, and transitioned to the Merit-Based Incentive Payment System (MIPS) in 2019 in accordance with the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).¹⁴⁷ Other ACA provisions designed to improve the coordination of care included a national pilot program to examine bundling payments “for integrated care during an episode of care” as well as a new program to “support the patient-centered medical home,” a model for the delivery of comprehensive primary care using a range of coordinated and interdisciplinary services designed to manage chronic conditions.¹⁴⁸

Perhaps the centerpiece of the volume-to-value-based transition was the creation of the Medicare Shared Savings Program (MSSP), which encouraged multilevel groups of health care providers to form accountable care organizations (ACOs) through which they would share accountability for the cost and quality of care for a group of Medicare beneficiaries.¹⁴⁹ Although the program has gone through several different iterations, the initial plan was for ACOs to start on a one-sided risk model in which they shared in savings if their per capita Medicare expenditures fell below a benchmark, and subsequently to transition to a two-sided risk model in which they shared both savings and losses.¹⁵⁰ The goals of the MSSP were nothing short of transformative: “to promote accountability for a patient population, coordinate items and services furnished to beneficiaries under Medicare Parts A and B, and encourage investments in infrastructure and redesigned care processes for high quality and efficient service delivery.”¹⁵¹

Despite these lofty goals, the ACA’s value-based provisions seemed to be at odds with the fraud prohibitions. Under many value-based arrangements, providers who generate referrals (such as physicians) and those who receive referrals (such as hospitals) would be working together to coordinate patient care in return for potential financial gain—behavior the fraud laws were designed to

146. § 1395ww(o)(2)(B)(i)(I); *Hospital Value-Based Purchasing Program*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Hospital-Value-Based-Purchasing-> (last updated Dec. 1, 2021).

147. § 1395w-4(p), (q) (original ACA value-based physician modifiers & MIPS respectively); Medicare Access and CHIP Reauthorization Act of 2015, Pub. L. No. 114-10, § 101(c), 129 Stat. 87, 92 (2015).

148. § 1395cc-4(a)(1) (bundled payments); § 256a-1(c)(2) (medical homes).

149. § 1395jjj.

150. *Final Rule Creates Pathways to Success for the Medicare Shared Savings Program*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Dec. 21, 2018), <https://www.cms.gov/newsroom/fact-sheets/final-rule-creates-pathways-success-medicare-shared-savings-program>.

151. Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 67,802, 67,824 (Nov. 2, 2011) (codified at 42 C.F.R. pt. 425).

prevent, at least in the FFS world.¹⁵² Indeed, a 2012 Government Accountability Office (GAO) study concluded that from the perspective of many providers, the challenges of implementing value-based incentive programs within the current fraud laws outweighed the potential benefits.¹⁵³ In response, HHS developed a process to waive the laws for ACOs if certain safeguards were present, including authorization by a governing body, a bona fide determination that the arrangement was reasonably related to the purposes of the program, and public disclosure.¹⁵⁴

Those efforts were enshrined into law at the very end of the Trump administration, which on November 20, 2020, finalized changes to the Stark, Anti-Kickback, and Beneficiary Inducements regulations to permanently allow certain value-based arrangements.¹⁵⁵ The new Stark exception for value-based arrangements provides varying levels of flexibility depending on the level of financial risk borne by the parties, ranging from full risk to “meaningful downside financial risk” to no or low risk.¹⁵⁶ The Anti-Kickback regulations include three new safe harbors addressing similar considerations, providing greater flexibility for participants willing to take on greater financial risk.¹⁵⁷ All three new safe harbors protect the exchange of in-kind remuneration, but monetary remuneration is only protected for arrangements involving at least “substantial downside financial risk.”¹⁵⁸ While the new Stark and Anti-Kickback exceptions are similar, due to inherent differences in the laws, the regulations are not identical; therefore, providers cannot assume that meeting the criteria under one statute will protect against violating the other.¹⁵⁹

152. Krause, *supra* note 140, at 854.

153. U.S. GOV'T ACCOUNTABILITY OFF., GAO-12-355, MEDICARE: IMPLEMENTATION OF FINANCIAL INCENTIVE PROGRAMS UNDER FEDERAL FRAUD AND ABUSE LAWS 36–37 (Mar. 2012).

154. Medicare Program; Final Waivers in Connection with the Shared Savings Program, 80 Fed. Reg. 66,726 (Oct. 29, 2015) (codified at 42 C.F.R. pt. 425).

155. Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, 85 Fed. Reg. 77,492 (Dec. 2, 2020) (codified at 42 C.F.R. pt. 411); Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 85 Fed. Reg. 77,684 (Dec. 2, 2020) (codified at 42 C.F.R. pts. 1001, 1003); Off. of Inspector Gen., Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 85 Fed. Reg. 77,684, 77,684 (Dec. 2, 2020).

156. 42 C.F.R. § 411.357 (2021).

157. Off. of Inspector Gen., *supra* note 155.

158. 42 C.F.R. § 1001.952 (ee), (ff) & (gg) (2021). The revisions also expanded the personal services and management contracts safe harbor to permit certain “outcomes-based payment,” § 1001.952(d)(2) (2021), and created a new safe harbor for “[a]rrangements for patient engagement and support to improve quality, health outcomes, and efficiency” for patients in value-based arrangements. § 1001.952(hh) (2021).

159. Compare 42 U.S.C. § 1320a–7b(b), with 42 U.S.C. § 1395nn.

Although the regulations finalized a process that began during the Obama administration, the timing of the announcement created difficulties. Indeed, it was unclear for several months whether the Biden administration intended to revoke the provisions, as is common with last-minute regulations finalized at the end of a predecessor's administration.¹⁶⁰ The rules were announced on November 20, 2020, with an effective date of January 19, 2021, just before President Biden took office—but they were not published in the Federal Register until December 2, 2020.¹⁶¹ The Congressional Review Act requires a period of sixty days to elapse between the effective date of a major rule and the rule's publication in the Federal Register or receipt by Congress.¹⁶² Although the November 20 announcement would have met the sixty-day threshold, the delay in publication until December 2 led GAO to conclude that the final rules were not in technical compliance with the Act.¹⁶³ Moreover, President Biden's Chief of Staff issued a memorandum on Inauguration Day requesting that executive agencies "consider postponing [several] rules' effective dates for 60 days from the date of this memorandum . . . for the purpose of reviewing any questions of fact, law, and policy the rules may raise."¹⁶⁴ In February 2021, however, an industry publication quoted a CMS statement that the Stark revisions were in fact in effect (with the exception of one provision that had a later effective date); while OIG has not made a similar statement, the revised safe harbors currently appear on the agency's website.¹⁶⁵

160. Sharece Thrower, *Regulatory Delay Across Administrations*, BROOKINGS (July 10, 2019), <https://www.brookings.edu/research/regulatory-delay-across-administrations/>.

161. *Medicare Program: Modernizing and Clarifying the Physician Self-Referral Regulations*, 85 Fed. Reg. 77,492, 77,492–682 (Dec. 2, 2020).

162. 5 U.S.C. § 801(a)(3)(A).

163. Letter from Shirley A. Jones, Managing Associate Gen. Couns., GAO, to The Hon. Chuck Grassley et. al., on Department of Health and Human Services, Centers for Medicare and Medicaid Services: Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations (Dec. 14, 2020) (on file at <https://www.gao.gov/products/b-332770>); Letter from Shirley A. Jones, Managing Assoc. Gen. Couns., GAO, to The Honorable Chuck Grassley et al., on Department of Health and Human Services, Office of Inspector General: Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements (Dec. 22, 2020) (on file at <https://www.gao.gov/products/b-332788>).

164. Memorandum from Ronald A. Klain, Assistant to the President and Chief of Staff, to Heads of Exec. Dep'ts and Agencies on Regul. Freeze Pending Rev. (Jan. 20, 2021).

165. *Is the New CMS Rule That Impacts Healthcare Valuations Now at Risk?*, BVR (Feb. 17, 2021), <https://www.bvresources.com/articles/bvwire/is-the-new-cms-rule-that-impacts-healthcare-valuations-now-at-risk> (quoting statement from CMS); *HHS Office of Inspector General Fact Sheet, Final Rule: Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements*, DEP'T HEALTH & HUM. SERVS. (Nov. 2020), <https://oig.hhs.gov/documents/compliance/836/factsheet-rule-beneficiary-inducements.pdf>.

There is a difference, however, between removing obstacles to the creation of innovative payment and delivery models, and a presumption that those models—because they generally are expected to improve quality of care and lower costs—will similarly reduce incentives for fraud. Above all, health care fraud is *opportunistic*, flourishing in the dark recesses where reimbursement meets reporting.¹⁶⁶ Under FFS, physicians may be tempted to “upcode” to more lucrative categories of care or charge for services that were not provided, and hospitals may be tempted to shift costs into categories that receive favorable payment.¹⁶⁷ Payment mechanisms drive the way in which fraud will be expressed in any particular reimbursement system.¹⁶⁸ Thus, experience suggests that rather than reducing overall fraud, value-based reimbursement will simply change the way in which fraud occurs.

Moreover, the Biden administration assumed office when this transition from volume-to valued-based payment was *incomplete*. Every reimbursement method contains incentives for providers to misrepresent *something* in order to increase payment.¹⁶⁹ Under the MSSP, for example, ACOs prosper if they report high quality of care and patient satisfaction in addition to lower costs.¹⁷⁰ Thus, there may be incentives for ACOs to misrepresent costs, to report a more highly-compensated patient mix, to report better outcomes (or downgrade initial assessments to make it appear patients have made progress), to cherry-pick the patients who are asked to complete satisfaction surveys, or to surreptitiously encourage riskier patients to opt out of the ACO altogether.¹⁷¹ Moreover, as initially created, the MSSP did not require ACO providers to be paid on a bundled or even a value-enhanced basis; participants were paid under the Medicare FFS program while also being eligible for shared savings, meaning that the fraud incentives inherent in volume-based FFS payment were still present.¹⁷² In essence, then, President Biden must confront the worst of both

166. Tracey A. Elliott & Joan H. Krause, *Introduction: Fraud and Abuse Law*, in THE OXFORD HANDBOOK OF COMPARATIVE HEALTH LAW 365, 365–66 (Tamara Hervey & David Orentlicher, eds., 2022) (describing how fraud is “universal, dynamic, and persistent”).

167. See, e.g., *United States v. Krizek*, 859 F. Supp. 5, 8 (D.D.C. 1994) (alleged billing for lengthier psychiatric treatment sessions than actually occurred); *Largest Health Care Fraud Case in U.S. History Settled: HCA Investigation Nets Record Total of \$1.7 Billion*, DEPT. JUST. (June 26, 2003), https://www.justice.gov/archive/opa/pr/2003/June/03_civ_386.htm (describing allegations that hospital chain engaged in cost reporting fraud schemes).

168. See Pamela H. Bucy, *Health Care Reform and Fraud by Health Care Providers*, 38 VILL. L. REV. 1003, 1049 (1993) (“In health care, like in everything else, the way we pay people affects the way they cheat.”).

169. *Id.*

170. Jessica L. Mantel, *Accountable Care Organizations: Can We Have Our Cake and Eat It Too?*, 42 SETON HALL L. REV. 1393, 1412–13 (2012).

171. See *id.* at 1425, 1427, 1432, 1434–35 (describing risks of undertreatment and “upstaging” of patient data).

172. 42 U.S.C. § 1395jjj(d)(a)(A).

worlds: traditional forms of fraud in the lingering FFS system, plus new forms of fraud unique to value-based payment.

C. Addressing Ongoing Fraud

Lest we forget, even amid a pandemic and an evolving health care reimbursement system, traditional forms of fraud continue to flourish. The Biden administration must contend not only with new forms of fraud, but also with the types of fraudulent activities that have long bedeviled the government. Fraud occurs in every corner of the health care industry: the 2020 HCFAC Annual Report, for example, highlighted nearly twenty different areas of enforcement, including ambulance services, durable medical equipment, electronic health records, home health services, hospitals, laboratories, nursing homes, physical and occupational therapy, prescription drugs, and substance abuse treatment.¹⁷³ According to a 2012 GAO report, the majority (60.6%) of civil investigations and almost half (49.2%) of criminal investigations focused on entities such as hospitals, home health providers, and medical facilities; physicians were the largest category of individual targets, comprising an estimated 15.4% of criminal and 12.1% of civil investigations.¹⁷⁴

One area of ongoing fraud concern is the pharmaceutical industry. Between 1991 and 2017, pharmaceutical manufacturers entered into 412 fraud settlements totaling \$38.6 billion.¹⁷⁵ The average federal financial penalty decreased significantly in 2016-2017 from a high in 2012-2013, with very few federal criminal penalties assessed and *qui tam* complaints responsible for fifty-four percent of federal settlements.¹⁷⁶ Common allegations against the industry include the payment of kickbacks to physicians in return for prescribing a company's products, unlawful promotion, and Medicaid drug pricing fraud.¹⁷⁷ Indeed, nearly every aspect of drug research, development, and sales has implicated fraud concerns, including not only improper activities designed to increase the sales of a product once it is on the market, but even the legitimacy of basic research studies.¹⁷⁸

173. See 2020 HCFAC Rep., *supra* note 53, at 14–30.

174. U.S. GOV'T ACCOUNTABILITY OFF., GAO-12-820, TYPES OF PROVIDERS INVOLVED IN MEDICARE, MEDICAID, AND THE CHILDREN'S HEALTH INSURANCE PROGRAM CASES 16–18, 25–27 (2012).

175. Sammy Almashat et al., *Twenty-Seven Years of Pharmaceutical Industry Criminal and Civil Penalties: 1991 Through 2017*, PUB. CITIZEN 4 (Mar. 14, 2018), <https://www.citizen.org/wp-content/uploads/2408.pdf>.

176. *Id.* at 10.

177. See generally *id.*

178. See, e.g., Kevin P. Hill et al., *The Advantage Seeding Trial: A Review of Internal Documents*, 149 ANNALS INTERNAL MED. 251, 251, 256 (2008) (describing “seeding trial” for Vioxx, designed to “seed” the market under the guise of studying a legitimate scientific research question); Sergio Sismondo, *Ghost Management: How Much of the Medical Literature is Shaped Behind the Scenes by the Pharmaceutical Industry*, 4 PLOS MED., Sept. 2007, at 1429, 1429

There is no sign that these concerns are waning. Based on data from Open Payments, the publicly available database created by the Physician Payments Sunshine Act, payments from manufacturers to physicians remain robust; moreover, there is growing anecdotal evidence that such payments—even if not designed as explicit kickbacks—are associated with physicians’ perhaps unintentional increased use of particular products.¹⁷⁹ Indeed, recent investigations indicate that the problem may be even more extensive in the medical device industry, despite the majority of investigations traditionally focusing on pharmaceutical manufacturers.¹⁸⁰ There also has been no shortage of allegations that manufacturers continue to offer more explicit incentives for physicians to use their products, including a November 2021 settlement with a company accused of offering gifts to physicians to induce them to prescribe the company’s opioid overdose antidote.¹⁸¹

Another area of activity that continues to draw scrutiny is pharmaceutical company funding of patient assistance programs, which are designed to help patients defray the cost of expensive brand-name drugs.¹⁸² When the companies that manufacture those drugs also fund nominally “independent” assistance programs, the government has warned of concerns that the companies are using their donations to steer patients toward their own products in violation of the Anti-Kickback Statute.¹⁸³ The DOJ has entered into several settlements over this practice, and is currently fighting a suit by Pfizer challenging the government’s interpretation of the Anti-Kickback Statute in this context.¹⁸⁴

(questioning studies that are “ghost-managed” by manufacturers and “ghost-written” by company staff while research publicly is attributed to independent medical experts.).

179. See, e.g., Ctrs. for Medicare & Medicaid Servs., *What is Open Payments?*, CMS.GOV, <https://www.cms.gov/OpenPayments> (last modified Feb. 3, 2022, 8:30 AM); Kosuke Inoue et al., *Association Between Industry Payments and Prescriptions of Long-Acting Insulin: An Observational Study with Propensity Score Matching*, PLOS MED., June 2021, at 1, 10; Amarnath R. Annapureddy et al., *Association Between Industry Payments to Physicians and Device Selection in ICD Implantation*, 324 J. AM. MED. ASS’N 1755, 1762 (2020); Deborah C. Marshall et al., *Trends in Industry Payments to Physicians in the United States from 2014 to 2018*, 324 J. AM. MED. ASS’N 1785, 1785 (2020).

180. See Alon Bergman et al., *Medical Device Firm Payments to Physicians Exceed What Drug Companies Pay Physicians, Target Surgical Specialties*, 40 HEALTH AFFS. 603, 604, 608 (2021).

181. *Kaléo, Inc. Agrees to Pay \$12.7 Million to Resolve Allegations of False Claims for Anti-Overdose Drug*, U.S. DEP’T. JUST. (Nov. 9, 2021), <https://www.justice.gov/usao-ma/pr/kal-o-inc-agrees-pay-127-million-resolve-allegations-false-claims-anti-overdose-drug>.

182. Publication of OIG Special Advisory Bulletin: Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70,623, 70,625 (Nov. 22, 2005).

183. *Id.*

184. See Sheng Liu et al., *Patient Assistance Programs for Prescription Drugs: Charities or Kickbacks?*, J. HEALTH & LIFE SCI. L. (July 31, 2021), <https://www.americanhealthlaw.org/content-library/journal-health-law/article/9b03b263-e910-48e4-847d-84c7a351ee23/patient-assistance-programs-for-prescription-drugs> (describing challenges); *Pfizer Inc. v. U.S. Dept. of Health &*

Another area that requires attention is the ongoing effort to use the fraud laws, among other tools, to address the opioid epidemic. The DOJ created an Opioid Fraud and Abuse Detection Unit in August 2017, designed to aggregate data to identify health care practitioners with questionable opioid prescribing practices.¹⁸⁵ The effort also created several dedicated assistant United States attorney positions focusing exclusively on prescription opioid-related fraud, working with other federal and state agencies to target health care providers who may be furthering the epidemic.¹⁸⁶ These efforts are continuing, with new indictments filed and no indication that the Biden administration intends to pull back on the initiative.¹⁸⁷

Fraud enforcement is proceeding on other fronts as well. The government continues to pursue entities who defraud Medicare and Medicaid, including recently intervening in a *qui tam* suit filed against Kaiser Permanente for submitting inaccurate diagnosis codes for patients in order to obtain additional reimbursement under Medicare Advantage, Medicare's managed care program.¹⁸⁸ Moreover, President Biden may have to weigh in on an effort by Senator Chuck Grassley—a major proponent of the FCA and critic of some of the Trump administration's efforts to scale back enforcement—to amend the FCA to make it easier for the government to prove that a misrepresentation is “material” and more difficult for the DOJ to arbitrarily dismiss *qui tam* complaints.¹⁸⁹ The Biden administration does not appear to have taken a position on the proposed changes, but should some future version of the bill advance to a successful floor vote, that will become necessary.

Overall, it appears the Biden administration has attempted to balance the need for protection against serious fraud schemes with the recognition that enforcement depends as much on the industry's willingness to comply as it does on the resources Congress is willing to devote to the problem—and a recognition that when it comes to fraud, simply issuing more threats may not always be the

Human Servs., No. 1:20 Civ. 04920 (S.D.N.Y. Sept. 30, 2021) (granting government's motion to dismiss).

185. 2017 HCFAC Rep., *supra* note 50, at 10.

186. 2020 HCFAC Rep., *supra* note 53, at 10.

187. See *Monmouth County Doctor Charged with Accepting Bribes and Kickbacks from Pharmaceutical Company in Exchange for Unlawfully Prescribing Fentanyl*, U.S. DEP'T JUST. (Nov. 4, 2021), <https://www.justice.gov/usao-nj/pr/monmouth-county-doctor-charged-accepting-bribes-and-kickbacks-pharmaceutical-company>.

188. See *Government Intervenes in False Claims Act Lawsuits Against Kaiser Permanente Affiliates for Submitting Inaccurate Diagnosis Codes to the Medicare Advantage Program*, U.S. DEP'T JUST. (July 30, 2021), <https://www.justice.gov/opa/pr/government-intervenes-false-claims-act-lawsuits-against-kaiser-permanente-affiliates>.

189. False Claims Amendments Act of 2021, S. 2428, 117th Cong. (2021) (as reported out of Committee on the Judiciary with amendment, Nov. 16, 2021).

answer.¹⁹⁰ President Biden has not been shy about creating new enforcement initiatives where needed. In October, the DOJ launched the Civil Cyber-Crime Initiative, a new effort to utilize the FCA “to pursue cybersecurity related fraud by government contractors and grant recipients” focusing on deficient cybersecurity protections, misrepresentation of cybersecurity practices, and violations of duties to monitor and report breaches.¹⁹¹ Yet the administration also appears committed to streamlining the voluminous amount of program-related information available to the health care industry, mounting an “OIG Modernization Initiative” designed to assure the government is “producing useful and timely resources that, among other things, advance the health care industry’s voluntary compliance and help prevent fraud, waste, and abuse.”¹⁹² Although it is too soon to tell, the administration’s efforts so far appear to signal a commitment to preventing fraud while also trying to assure a fair playing field for the industry.

IV. CONCLUSION

The Biden administration must confront a health care fraud threat that is complex and relentless. The pandemic gave health care providers not only the funds needed to stay solvent, but also incentives to misappropriate those funds for unintended purposes.¹⁹³ The transition from volume-to value-based payment is incomplete, leaving gaps in which both new and old forms of fraud may flourish.¹⁹⁴ Moreover, traditional forms of fraud in the pharmaceutical industry and beyond show no signs of abating.¹⁹⁵

Although the administration initially remained relatively quiet regarding fraud, seemingly content to continue initiatives started by President Trump, the DOJ, OIG, and CMS have started to roll out new guidance and undertake new efforts, such as the Cyber-Crime Initiative and the COVID-19 Fraud

190. See, e.g., Krause, *supra* note 19, at 210–13 (warning of the importance of an enforcement approach that the provider community accepts as legitimate).

191. Deputy Attorney General Lisa O. Monaco Announces New Civil Cyber-Fraud Initiative, U.S. DEP’T JUST., (Oct. 6, 2021), <https://www.justice.gov/opa/pr/deputy-attorney-general-lisa-o-monaco-announces-new-civil-cyber-fraud-initiative>.

192. OIG Modernization Initiative to Improve Its Publicly Available Resources – Request for Information 86 Fed. Reg. 53,072, 53,072 (Sept. 24, 2021). As another example, the Biden administration updated the protocol for providers to self-disclose fraud violations in exchange for leniency. Off. Inspector Gen., *Updated: OIG’s Health Care Fraud Self-Disclosure Protocol*, U.S. DEP’T HEALTH & HUM. SERVS. (Nov. 8, 2021), <https://oig.hhs.gov/documents/self-disclosure-info/1006/Self-Disclosure-Protocol-2021.pdf>.

193. See discussion, *supra* Section III.A.

194. See discussion, *supra* Section III.B.

195. See discussion, *supra* Section III.C.

Enforcement Task Force.¹⁹⁶ In many ways, these efforts harken back to the enforcement priorities of the Obama administration, reinvigorating the DOJ's focus on the role of individuals in corporate crime and signaling a potentially less industry-friendly approach.¹⁹⁷ The exigencies of the pandemic, however, are likely to constrain President Biden's ability to stray far from the focus on COVID-19, at least for the foreseeable future.

196. *Deputy Attorney General Lisa O. Monaco Announces New Civil Cyber-Fraud Initiative*, *supra* note 191; *Attorney General Announces Task Force to Combat COVID-19 Fraud*, *supra* note 120.

197. *See* discussion, *supra* Section II.D.