



First in a Series



WHITE PAPER

March 2024

2023 False Claims Act Enforcement in Health Care and Life Sciences, Part I

In February 2024, the Department of Justice (“DOJ”) announced the results of its 2023 False Claims Act (“FCA”) enforcement efforts. Through those efforts, the government obtained more than \$2.6 billion in overall recoveries, and of that amount, \$1.8 billion came from health care and life sciences (“HCLS”) stakeholders alone.

This *White Paper*—first in a three-part series—focuses on FCA enforcement in the HCLS industry. We will examine the 2023 results, how they differ from previous years in terms of monetary recoveries and DOJ’s case mix, as well as the evolution of DOJ’s priorities and judicial decisions impacting this area. In particular, Part I provides an overview of the 2023 recoveries; analyzes enforcement trends and priorities relating to the Anti-Kickback Statute and Stark Law, Medicare Advantage, cybersecurity, pandemic fraud, and private equity; and looks ahead to what we can expect to see in 2024.

Parts II and III, to be issued separately, will cover case highlights for notable 2023 FCA resolutions in the HCLS space and in-depth discussions of key FCA developments from the bench.

OVERVIEW: 2023 HEALTH CARE FRAUD FALSE CLAIMS ACT RECOVERIES

In the last two years, health care fraud FCA recoveries by DOJ have reverted to the mean.¹ The year 2021 was a high-water mark when DOJ [secured more than \\$5 billion](#) in health care fraud-related FCA recoveries—\$3 billion of which came from manufacturer settlements. In 2022, we saw a significant decline in health care recoveries from \$5 billion to \$1.7 billion, and 2023 largely continued the pattern. Without high-dollar manufacturer settlements to drive outsized results, the annual health care FCA recoveries for the last two years settled back into familiar territory—[around \\$2 billion a year](#).

Like the monetary recoveries, the types of FCA-health care cases resolved by DOJ in 2023 cover familiar ground—with the Anti-Kickback Statute (“AKS”), Stark Law, and Medicare Advantage (Part C) enforcement leading the pack. Specific initiatives, like application of the FCA to pandemic-related fraud and cybersecurity issues affecting the federal government, are ongoing but not yet showing substantial results in terms of FCA recoveries. Non-health care FCA recoveries saw an uptick, but, as usual, health care fraud constituted the lion’s share of FCA recoveries. Below, we summarize these enforcement trends and will cover case highlights in Part II, our second installment of this *White Paper*.

2023 also brought significant FCA developments from the bench. The U.S. Supreme Court has weighed in on two high-stakes FCA issues: scienter and DOJ’s power to dismiss *qui tam* complaints over relator objections. In *United States ex rel. Schutte v. SuperValu Inc.*, the Supreme Court reversed the Seventh Circuit; the Court ruled that a defendant’s subjective state of mind can be sufficient to establish scienter under the FCA and rejected the view that scienter could be precluded simply by showing the defendant’s actions were “consistent with any objectively reasonable interpretation” of the regulatory requirements underlying an FCA claim.

The Supreme Court also resolved questions relating to DOJ’s authority to dismiss *qui tam* complaints over the relator’s objection: In *United States ex rel. Polansky v. Executive Health Resources, Inc.*, the Court confirmed that the government may dismiss over the relator’s objection even if the government has initially declined to take over the case. At the same time, the

Court ruled that the standard to be applied to a government motion to dismiss should be the standard that governs voluntary dismissal of suits in ordinary civil litigation (i.e., Rule 41(a) of the Federal Rules of Civil Procedure). Finally, the circuit split over causation in AKS-based FCA cases has widened, with the Supreme Court declining to take up the issue in last year’s Term. *Schutte, Polansky*, the growing “causation” circuit split, and other notable decisions will be discussed in detail in an upcoming installment of Jones Day’s series on FCA litigation and enforcement in 2023.

Finally, in 2023 federal officials have signaled coordinated investigations concerning the role of investor-owned entities, including private equity in the health care space, as well as notable changes in various DOJ and HHS-OIG policies and practices affecting [FCA enforcement](#)—such as how DOJ accounts for cooperation credit in FCA matters, the incidence of admissions in various FCA resolutions around the country, and updated HHS-OIG compliance guidance.

Looking Ahead: DOJ Priorities for FCA Enforcement in 2024

In February 2024, Principal Deputy Assistant Attorney General Brian Boynton [previewed](#) DOJ’s FCA enforcement priorities for the coming year.² If predictions hold true, 2024 will likely look similar to 2023 with perhaps a few twists. As before, DOJ’s stated top priorities include COVID- and cyber-related fraud, as well as a number of health care-specific initiatives.

Within health care, Principal Deputy Boynton highlighted DOJ’s ongoing interest in pursuing cases concerning alleged financial inducements for providers (i.e., AKS and Stark Law violations), reported misconduct in connection with nursing homes and elder care, and Medicare Part C. Medicare Part C and the role that purportedly inflated diagnosis codes play in terms of the capitation rates paid by the Centers for Medicare & Medicaid Services (“CMS”) are likely to be an increasing focus, given the growth of that program. However, in addition to focusing on insurers, DOJ also promises to include an examination of the role that vendors and providers play in the diagnoses that are submitted to the government.

DOJ also announced that it anticipates pursuing matters against “third parties that cause the submission of false claims”—including such actors as electronic health record

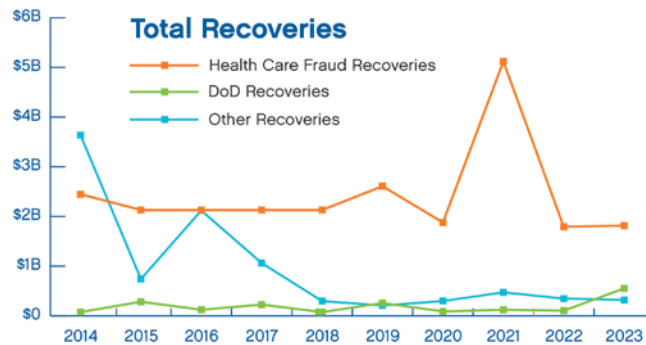
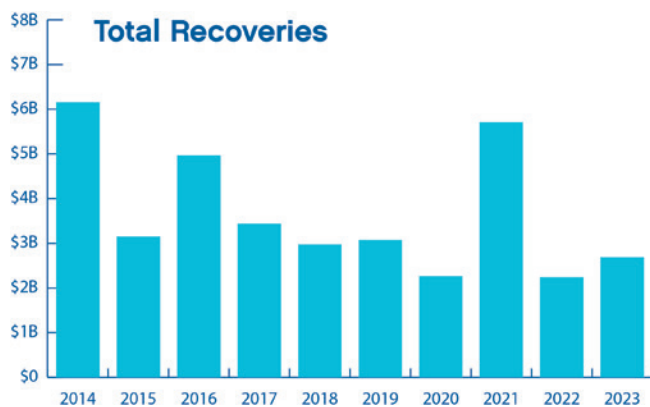
vendors, coding consultants, private equity, and venture capital. While DOJ acknowledged that third-party actors can play “positive roles” in the health care industry, the crux of its message was that it will be scrutinizing the conduct of such non-traditional health care actors.

It is noteworthy that drug pricing was omitted in the Principal Deputy’s forecast for 2024 FCA enforcement. While much of the current DOJ enforcement in this area appears to favor competition-related theories, given the ongoing attention to this topic and the ever-present interest from the relators’ bar, it is likely we will see more activity in this space as well.

2024 may also prove eventful for FCA rulings. With cases on causation making their way up to the courts of appeal, the circuit split on causation may continue to grow, perhaps setting up opportunities for the Supreme Court to tackle this long-simmering issue. The Supreme Court will also weigh in on the Chevron doctrine, which could have a wide-ranging impact on arguments regarding the legal construction of regulations underlying FCA cases.

HEALTH CARE FCA MONETARY RECOVERIES AND NEW MATTER TRENDS

As in 2022, DOJ’s 2023 health care fraud FCA recoveries were dramatically lower than the 2021 high. Recoveries are slightly higher than last year at \$1.8 billion, but still on the lower end of typical health care FCA recoveries.³



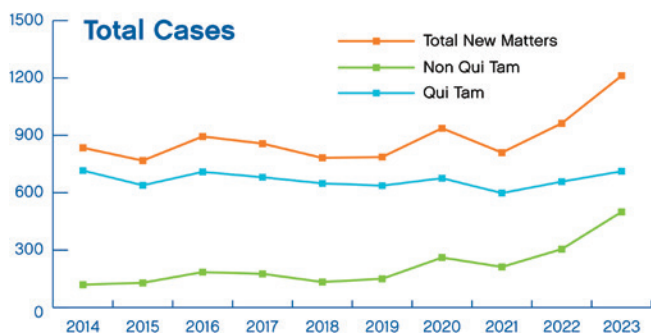
Indeed, compared to the last 10 years, 2023 recoveries are of a decidedly lower magnitude than historical numbers. Excluding 2021 as an outlier, health care FCA recoveries have stayed between \$1.7 billion and \$2.7 billion for the last 10 years.⁴ And only one of the last 10 years (2022) resulted in lower health care recoveries than 2023.⁵ This is true despite the fact that in 2023, the government and *qui tam* relators were party to 543 settlements and judgments, which is the highest number of settlements and judgments in a single year.⁶ While the number of resolutions jumped 54% between 2022 to 2023, the monetary recoveries increased only 20%, underscoring the point that more cases do not necessarily bring higher monetary recoveries.

In its 2023 roundup, DOJ did not provide clear insight into the reasons for lower 2023 FCA health care recoveries. However, it does seem likely that at least part of the explanation relates to the diversion of investigative resources to pandemic fraud, which at this time appears to be still focusing predominantly on criminal cases and small-dollar FCA matters. In its “Justification” for its FY 2025 budget request, the Department of Health and Human Services—Office of Inspector General (“HHS-OIG”) stated that it has “faced an explosion of COVID-19–related fraud, necessitating the difficult choice to divert investigative resources from other viable cases to protect HHS programs and consumers from fraud. Delayed cases included civil False Claims Act cases, which are a primary way the Government recovers misspent funds.” HHS-OIG indicated that due to resource limitations, it was unable to pursue 300–400 “viable” cases on an annual basis.

The government’s response to COVID has also affected DOJ’s allocation of resources and necessitated a request for increased funding to, among other things, bolster its pandemic

enforcement work. Whether increased funding materializes and translates into a significant expansion of FCA health care enforcement work remains to be seen.

Each year, DOJ also includes statistics on the number of new matters. While the statistics can create more questions than they answer, they can give a sense of the direction enforcement activity is taking.



As the table above indicates, from 2019 to 2022, the overall number of new matters oscillated between 787 and 963. In 2023, new matters significantly increased, coming in at 1,212. Note that the increase is largely attributable to cases *initiated by DOJ*, i.e., non-*qui tam* matters. Over three years, from 2019 to 2022, the number of non-*qui tam* cases doubled from 150 to 305. Then in 2023, the number of matters initiated by DOJ jumped from 305 to 500. Although the statistics do not identify the sources of these matters, they can come from a variety of places, including agency referrals, news articles, congressional hearings, and, increasingly, data mining.

In contrast to the dramatic increase in the number of DOJ-initiated matters is the relatively steady number of *qui tam* matters filed by whistleblowers: Since 2018, the number of *qui tam* matters filed annually has ranged between 598 and 676. The number of filed *qui tam* complaints increased only slightly this past year to 712.

This year's fraud statistics also demonstrate that DOJ and the relator's bar are continuing to increase the number of non-health care FCA matters. DOJ's data breaks down new matters into three categories: Health and Human Services ("HHS"), Department of Defense ("DOD"), and "Other" (which can capture any other non-HHS/DOD FCA cases such as those relating to, e.g., Paycheck Protection Program ("PPP") loans and Economic Injury Disaster Loans, NIH grants, or any non-DOD/

HHS government contracts and government grants). In 2023, new HHS and DOD matters remained steady. Not so for the "Other" category. In past years, "Other" cases have run a distant third in terms of monetary recoveries new matters. And they still do, but the gap is shrinking.

The number of "Other" new matters nearly doubled from 226 in 2019 to 426 in 2022. In 2023, the number of "Other" new matters leaped up to 702. Time will tell whether these new matters will be similar to the relatively low-value pandemic fraud cases that we have seen in the last few years or lead to more substantial recoveries.

SUMMARY OF 2023 FALSE CLAIMS ACT HEALTH CARE LIFE SCIENCES ENFORCEMENT TRENDS

As an initial matter, cases from 2023 are as notable for what we don't see as for what we do. Controlled substance cases, along with foundation copay matters, did not yield significant recoveries. DOJ is still embroiled in ongoing litigation in the area,⁷ but the lack of 2023 recoveries suggests that further substantial recoveries by the government may depend on DOJ's success with the courts.

We also see little in the telemedicine-FCA arena. Although Deputy Assistant Attorney General Michael Granston previewed in 2020 that FCA enforcement in the telemedicine space would be forthcoming, the [public resolutions](#) have been overwhelmingly criminal in nature.⁸ Indeed, in DOJ's announcements regarding 2023 FCA recoveries and 2024 FCA enforcement priorities, telemedicine is absent.

Finally, although multiple federal agencies have signaled an intent to review private equity firms and other investor-owned/operated health care entities, we did not see notable FCA settlements in 2023. Nonetheless, federal officials, including DOJ, HHS-OIG, the Federal Trade Commission ("FTC"), Senator Grassley, and the White House, expressed an intent to keep the spotlight squarely focused on private equity and signaled robust scrutiny to come. DOJ's most recent statements regarding investor scrutiny are discussed in an upcoming installment of Jones Day's series on FCA litigation and enforcement in 2023.

Health care resolutions that were announced in FY 2023 suggest a return to the FCA basics, for now. As detailed below, the cases generally come from a familiar range of health care/life science stakeholders: namely, hospitals and health systems, large providers, manufacturers, electronic health records vendors, and increasingly, health plans. In addition, the matters are based on fairly typical legal theories—violations of the AKS and/or the Stark Law, medically unnecessary services/devices, upcoding, underpayment of rebates, and inflation of diagnosis codes by Medicare Advantage Organizations (“MAOs”).

MAO Investigations and Litigations. MAO investigations and litigations resulted in substantial resolutions for 2023, and, according to DOJ, we can expect to see more of these. As detailed below, DOJ’s 2023 results include two notable settlements with MAOs, totaling nearly \$200 million, as well as a criminal indictment. Given the burgeoning number of Medicare beneficiaries enrolled in Medicare Advantage (“MA”) plans, DOJ has [signaled an intention](#) to continue focusing attention and substantial resources in this direction.

AKS Investigations and Litigations. AKS investigations and litigations have consistently constituted a substantial portion of annual FCA recoveries; 2023 is no different, with AKS matters constituting close to half of the health care FCA recoveries. While the case was not referenced in DOJ’s press release for 2023 recoveries, DOJ obtained a [\\$487 million judgment](#) in an AKS matter litigated out of the District of Minnesota in May 2023. DOJ also entered into a large handful of smaller AKS-based settlements covering [hospitals](#), [physician practices](#), and electronic health record companies (including [settlements for \\$31 million](#) and [\\$45 million](#)), which collectively exceeded \$250 million. Notably, at the end of calendar year 2023, DOJ also obtained a [\\$345 million settlement](#) for alleged Stark Law violations that represents “the largest False Claims Act settlement based on Stark Law violations in the history of the Department of Justice.”

These settlements align with DOJ’s recent announcement that AKS and Stark Law matters are a priority area for its enforcement efforts in 2024. In its press release detailing recoveries from FY 2023, DOJ also singled out a number of FCA resolutions involving allegedly unnecessary services and standard care, including in long-term care facilities, which align with DOJ’s priorities for 2024 as well.

Cybersecurity and Pandemic FCA Activity. Cybersecurity and pandemic fraud have been areas in which DOJ has promised significant FCA enforcement.⁹ While we have seen significant activity in both spaces, actual FCA resolutions—particularly those affecting the health care sector—have so far been relatively few in number and, in terms of recoveries, on the low end of the spectrum. With respect to cybersecurity, the [2021 initiative](#) is still in its beginning stages, with a small handful of DOJ resolutions from 2022–2023, two of which are in the health care space and for amounts on the lower end of the monetary scale.¹⁰ However, based on what Jones Day is seeing in this space and further [public statements](#) from DOJ officials, we would expect to see additional cases, including in the health care sector, in 2024 and beyond.

With respect to pandemic fraud, DOJ’s criminal enforcement efforts are significant,¹¹ but FCA resolutions have so far been modest in amount and largely related to PPP cases, with relatively few relating to COVID-health care fraud. In 2022, [DOJ announced](#) only 35 COVID-FCA matters, with \$6.8 million in total recoveries. The number of settlements and the amount of monetary recoveries increased almost eight-fold in 2023, with DOJ resolving approximately 270 COVID-FCA matters in connection with PPP loans and recovering collectively [\\$48.3 million](#). Even with this increase, the overall contribution of COVID-FCA cases to DOJ’s 2023 annual FCA recoveries is small—indeed, on average, the COVID-FCA cases resulted in settlements of less than \$200,000 each. Further, of these 270 FCA resolutions, only a handful were in the health care space. However, as the PPP fraud cases wind down, we may see an uptick in FCA resolutions involving more complex health care issues.

NOTABLE DOJ/HHS POLICIES, PROPOSED LEGISLATIVE CHANGES, AND HHS GUIDANCE IMPACTING FCA MATTERS AND EXPOSURE

Cooperation Credit in False Claims Act Cases

A number of 2023 FCA settlements are shedding some light on the long-standing issue of how DOJ is implementing cooperation credit in FCA cases—and to what extent cooperation may generate quantifiable benefits. As background, in May 2019, DOJ [rolled out](#) formal guidance (entitled “DOJ’s Guidelines for

Taking Voluntary Disclosure, Cooperation, and Remediation into Account in False Claims Act Matters” and discussed by Jones Day [here](#)) in the Justice Manual that speaks to how cooperation credit would be handled for civil FCA matters. See [JM § 4-4.112](#). The policy revised and consolidated guidance that had appeared in various DOJ memos and speeches that appeared from 2015 to 2019. And despite expressions of frustration from the defense bar as to its limitations, the FCA cooperation credit policy has remained unchanged since it was issued in 2019.

That policy set forth guidelines for how “credit will be provided,” but included little clarity on that topic. The policy enumerated various types of cooperation that could be worthy of credit, including, e.g., voluntary disclosures and identifying individuals “substantially involved in” the conduct. However, the policy fell short on detailing the credit to be provided—for instance, what type and how much credit could a company receive if it did cooperate? While the policy generally indicated that credit could take the form of a reduction in the multiplier or penalties DOJ sought in an FCA case, it provided no further detail or quantification.

Similarly, the policy touted nonmonetary forms of credit (such as public acknowledgment of cooperation, conveying the company’s cooperation and remediation to the relevant agency, and assisting in resolving *qui tam* litigation with relatives), but gave no sense of when such “awards” might be warranted. Indeed, the Justice Manual made clear that the award of any credit was entirely within DOJ’s “discretion.” There has also been little in FCA settlement precedent that shed light on how or whether cooperation—or acceptance of responsibility—favorably impacted resolutions.¹² As a result, companies proactively conducting internal investigations or responding to a False Claims Act investigation have had limited guidance or concrete precedent to inform a risk–benefit analysis on the actual value of cooperation and disclosure.

More recently, however, DOJ has entered into various FCA resolutions that put some flesh on the bone in terms of whether cooperation truly provides quantifiable value for the company. In 2023, DOJ entered into four settlements that resulted in public acknowledgement of cooperation and provided some clues about whether the cooperation had a monetary benefit.

In these resolutions, DOJ credited the company for its cooperation/self-disclosure, and in three of these cases, explicitly acknowledged that the companies received “credit” under “DOJ’s Guidelines for Taking Voluntary Disclosure, Cooperation, and Remediation into Account in False Claims Act Matters, Justice Manual §4-4.112.”¹³

These settlements and related press releases also detailed aspects of the cooperation and remediation, which included, e.g.:

- A written disclosure
- “Identifying individuals” involved in or responsible for the conduct
- “Performing and disclosing the results of an internal investigation”
- “Disclosing relevant facts and material not known to the government”
- Attribution of the facts to “specific sources”
- Providing “regular updates” on its independent investigation and “rolling disclosures of relevant information”
- “Providing information relevant to potential misconduct by other individuals and entities”
- “Assisting in the determination and recovery of the losses.”¹⁴

So does cooperation have tangible value? Recognition of cooperation can be significant—a concrete acknowledgment by DOJ of the company’s cooperation and/or remediation of problematic conduct can have intangible, but significant, value—in terms of future public contracts, investor opinion, and simply from a reputational perspective.

But is there monetary value? To be sure, uncertainty remains, as none of the settlements explicitly provides information on the multiplier or any penalty that was applied by the government to reach the settlement amount. However, the settlement agreements contain provisions that allow limited inferences about how cooperation impacted the handling of multipliers and penalties to be made.

In particular, in each settlement agreement, a portion of the settlement amount is designated as “restitution,” which for tax purposes represents the amount the government is willing to characterize as “compensatory,” i.e., single damages under the

FCA. Based on the ratio of “settlement amount” to “restitution” (and assuming no penalties), it appears that the FCA damages multiple obtained by the government ranged from 1.5 to 1.75.

To put this in context, the government is entitled to treble damages under the FCA, so a multiplier of roughly half that amount would seem to be a material advantage. However, a pre-litigation FCA resolution with the government typically results in a multiplier of 2, give or take and depending on the circumstances. So the amount of “credit” would seem to be relatively slight from the perspective of a damages multiplier.

However, the critical question of how cooperation may have affected other key resolution factors remains—for instance, does cooperation/remediation affect the method for calculating single damages or the resolution of any corporate integrity-type issues? Experienced practitioners have a sense of how cooperation may set the stage for a more-favorable single damages methodology, as well as how cooperation and remediation affect the relevant agency’s appetite for a CIA, but unless and until there is more transparency, this determination remains more art than science.

Incidence of Admissions as Condition of Settlement

The U.S. Attorney’s Offices in the Southern District of [New York](#) and the District of [Massachusetts](#) have long been known for their regular practice of requiring settling companies to make admissions as a condition of resolving FCA matters, and that practice continued.

In 2023, we saw additional U.S. Attorney’s Offices incorporating admissions into their settlements in some limited instances as well. U.S. Attorney’s Offices in the [Eastern District of Washington](#), the [Northern District of Georgia](#), the [Northern District of New York](#), and the [Northern District of Texas](#) each entered into settlement agreements that included some degree of admissions. Notably, the settlement agreement with the Northern District of Texas stemmed from a self-disclosure by a dermatology management company following an acquisition, and the admissions focus on a particular agreement to direct referrals. This settlement agreement also included an express statement of cooperation under Section 4-4.112 of the Justice Manual.

Whether these additional U.S. Attorney’s Offices implemented admissions in these cases for particularized reasons or whether the Offices are on the road toward making admissions a regular requirement for a consensual resolution remains to be seen.

PROPOSED FALSE CLAIMS AMENDMENTS ACT OF 2023

In July 2023, a [bipartisan group](#) of senators, led by Senator Grassley (R-Iowa), introduced the “[False Claims Amendments Act of 2023](#),” threatening more rigid applications of the FCA against government contractors. Building on [Senator Grassley’s 2021 proposal](#), the legislation targets the Supreme Court’s test for materiality articulated in *Escobar*. In that case, the Court held, among other things, that the government’s continued payment of claims despite actual knowledge of a violation under the FCA is strong evidence against a finding of materiality. 579 U.S. 176, 178 (“If the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material.”).

In the wake of *Escobar*, courts have varied in how they have applied this factor when enforcing the FCA’s materiality standard. Compare *U.S. ex rel. Harman v. Trinity Industries, Inc.*, 872 F.3d 645 (5th Cir. 2017) (finding the government’s awareness of alleged noncompliance with testing protocols yet continued payments provided “very strong” evidence that certification inconsistencies were not material) with *U.S. ex rel. Campie v. Gilead Sciences, Inc.*, 862 F.3d 890 (9th Cir. 2017) (finding that relators sufficiently pleaded materiality and agreeing that “read[ing] too much into the FDA’s continued approval—and its effect on the government’s payment decision—would be a mistake”).

In an attempt to curtail *Escobar*’s interpretation of materiality, the proposed Amendment would provide that “the decision of the Government to forego a refund or to pay a claim despite actual knowledge of fraud or falsity shall not be considered dispositive if other reasons exist for the decision of the Government with respect to such refund or payment.” If

passed, the Amendment would reduce the weight of the government's continued payment to a materiality analysis, likely making it more difficult for defendants to prevail at the motion to dismiss and summary judgment stages.

In addition, the Amendment would extend the FCA's anti-retaliation protections for whistleblowers to post-employment retaliation. It would also require the U.S. Government Accountability Office to study the benefits and challenges of enforcement efforts and report on the amounts recovered under the FCA since the 1986 amendment.

Not a word has been heard from Congress since the proposed False Claims Amendments Act of 2023 was sent to the Senate and House Judiciary Committees on July 25, 2023, and November 25, 2023, respectively.

HHS-OIG Compliance Guidance for 2023

Since at least 1998, when HHS-OIG issued "[Compliance Program Guidance for Hospitals](#)," the agency has issued a [series](#) of compliance guidance documents for the health care and life science industries. As HHS-OIG acknowledges, the health care industry and entities involved in the industry have evolved, signaling the need for regulatory authorities to adapt and respond. Starting in 2023 and moving forward, HHS-OIG's guidance also promises to evolve. In April 2023, HHS-OIG [announced](#) plans to "improve and update" its existing compliance program guidance documents ("CPGs") and to provide new industry segment-specific CPGs ("ICPGs") for "segments of the health care industry or entities involved in the industry that have emerged in recent years."

As promised, HHS-OIG updated its CPGs in November 2023, publishing [General Compliance Program Guidance](#) ("GCPG") as a guide for the health care compliance community and other health care stakeholders. The GCPG is voluntary, non-binding guidance that discusses general compliance risks and compliance programs and provides information about relevant federal laws, compliance program infrastructure, OIG resources, and other information useful to understanding health care compliance. The GCPG also includes an overview of relevant federal laws, including OIG's interpretation of the FCA, as well as other health care statutory and regulatory requirements, such as the AKS and Stark Law.

Further reinforcing the connection between FCA enforcement and compliance, HHS-OIG expressly observed the intersection between quality and False Claims Act concerns: "Besides patient harm, quality and patient safety concerns, such as excessive services and medically unnecessary services, can lead to overpayments and may cause False Claims Act liability."

Jones Day is following the HHS-OIG's rollout of its updated compliance guidance and provided [commentary](#) on the GCPG when it was issued.

In February 2024, HHS OIG [announced](#) that it anticipates publishing guidance documents on the first two ICPGs—addressing MA and nursing facilities—and that the following two ICPGs will address hospitals and clinical laboratories. The agency publicly called for feedback related to these industry segments prior to the publishing of this guidance. Jones Day will be reporting on HHS-OIG activity regarding the upcoming ICPGs at various intervals.

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ENDNOTES

- 1 See [False Claims Act Settlements and Judgments Exceed \\$2.68 Billion in Fiscal Year 2023](#) (attaching Fraud Statistics Overview, October 1, 1986–September 30, 2023).
- 2 See [Principal Deputy Assistant Attorney General Brian M. Boynton Delivers Remarks at the 2024 Federal Bar Association's Qui Tam Conference](#) (Feb. 22, 2024).
- 3 See [False Claims Act Settlements and Judgments Exceed \\$2.68 Billion in Fiscal Year 2023](#) (attaching Fraud Statistics Overview, October 1, 1986–September 30, 2023).
- 4 *Id.*
- 5 *Id.*
- 6 *Id.*
- 7 DOJ has remained involved in both controlled substance and foundation copay areas. See, e.g., *U.S. ex rel. White v. Rite Aid Corp.*, No. 1:21-cv-1239 (N.D. Ohio Mar. 13, 2023) (DOJ intervened in 2023, alleging improper controls for controlled substance prescriptions); *United States v. Teva Pharms. USA, Inc.*, No. 23-8026 (1st Cir. Nov. 11, 2023) (DOJ brought suit against defendants for alleged violations of the FCA and AKS, claiming defendants used foundations to cover the Medicare copays for their multiple sclerosis drugs). See also *In re Endo Int'l plc*, No. 7:22-bk-22549 (S.D.N.Y. Bankr. Feb. 28, 2024) (in February 2024, DOJ entered into a settlement resolving criminal and civil matters relating to claims asserted in Endo's Chapter 11 bankruptcy action alleging improper marketing of controlled substances).
- 8 See [Remarks by Deputy Attorney General Lisa H. Miller](#) at the American Bar Association's 33rd Annual National Institute on Health Care Fraud (May 4, 2023) (Deputy Assistant Attorney General Lisa Miller highlighting the Health Care Fraud unit, which has charged 163 defendants in connection with telemedicine schemes, including 40 medical professionals, involving more than \$4.75 billion billed, and \$1.65 billion paid).
- 9 See, e.g., DOJ Press Release, ["False Claims Act Settlements and Judgments Exceed \\$2 Billion in Fiscal Year 2022"](#) (discussing DOJ's "new enforcement priorities, including fraud in pandemic relief programs and alleged violations of cybersecurity requirements in government contracts and grants").
- 10 See, e.g., ["Medical Services Contractor Pays \\$930,000 to Settle False Claims Act Allegations Relating to Medical Services Contracts at State Department and Air Force Facilities in Iraq and Afghanistan,"](#) U.S. Department of Justice (March 8, 2022). Notably, a whistleblower litigated and resolved a non-intervened cybersecurity case in 2022; ["Jelly Bean Communications Design and its Manager Settle False Claims Act Liability for Cybersecurity Failures on Florida Medicaid Enrollment Website,"](#) U.S. Department of Justice (March 14, 2023).
- 11 For instance, 2023 saw the launch of two additional "COVID-19 Fraud Enforcement Strike Forces"—one in Colorado and one in New Jersey—to supplement the three strike forces already active in California, Florida, and Maryland. ["Justice Department Announces Results of Nationwide COVID-19 Fraud Enforcement Action,"](#) U.S. Department of Justice (Aug. 23, 2023). See also ["Justice Department Announces Results of Nationwide COVID-19 Fraud Enforcement Action,"](#) U.S. Department of Justice (August 23, 2023).
- 12 Jacob Elberg, "Health Care Fraud Means Never Having to Say You're Sorry," 96 Wash. L. Rev. 371, 406 (2021) ("details of [False Claims Act] resolutions give observers reason to be skeptical that cooperation is in fact meaningfully rewarded by DOJ in the settlement process.").
- 13 See, e.g., [Settlement Agreement](#) (acknowledging cooperation credit under JM §4-4.112); [Settlement Agreement](#) (acknowledging cooperation credit under JM §4-4.112); ["Dermatology Management Company to Pay \\$8.9 Million to Resolve Self-Reported False Claims Act Liability,"](#) U.S. Attorney's Office Northern District of Texas (September 13, 2023) (crediting company for voluntary disclosure).
- 14 In two of these 2023 settlements, the companies also made certain admissions. See, e.g., ["Lab Billing Company Settles False Claims Act Allegations Relating to Unnecessary Respiratory Panels Run on Seniors Receiving COVID-19 Tests,"](#) U.S. Department of Justice (June 16, 2023).

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