



HEALTHCARE ENFORCEMENT AND COMPLIANCE

A LOOK AT
2023 TRENDS

Introduction

Regulatory and enforcement agencies are using more sophisticated tactics to identify and combat healthcare fraud, including data analytics and inter-agency initiatives, and leveraging the False Claims Act (FCA) – the government’s primary civil fraud enforcement tool – to do so. This overview summarizes some of the most notable FCA investigations, settlements, and judgments in 2023 so far, including cases and trends relating to Medicare, Medicaid, and TRICARE and involving claims for services not rendered, unnecessary services, substandard care, upcoding, unlawful kickbacks and bribes, and improper marketing and co-management arrangements.

In addition to the FCA, the U.S. Department of Justice (DOJ), U.S. Department of Health and Human Services Office of Inspector General (HHS-OIG), and other federal and state enforcement and regulatory agencies are pursuing actions using a variety of civil, criminal, and administrative laws to combat fraud, waste, and abuse in the healthcare industry.

This summary, based on Barnes & Thornburg’s comprehensive [2023 Healthcare Enforcement and Compliance Mid-Year Report](#), provides a snapshot of the most noteworthy legal developments, civil and criminal enforcement actions, industry guidance, and government policy updates throughout the first half of 2023. Barnes & Thornburg anticipates issuing its Annual Healthcare Enforcement and Compliance Report covering all of 2023 early next year.

Healthcare Fraud Enforcement Trends

It is crucial for healthcare entities to ensure they are familiar with current enforcement trends and reflect those enforcement priorities in their compliance programs to stem potential fraud, waste, and abuse.

Several notable trends have emerged in 2023 thus far, including:



A high number of FCA settlements and judgments, including a number of smaller-value recoveries, demonstrating the government’s focus not only on systemic fraud but also on small-scale fraud and low-profile actors



COVID-19-related healthcare fraud, including false billings to, and theft from, federally funded COVID-19 programs



Fraud related to telehealth/telemedicine



Data privacy, cybersecurity, and access to health records issues











Fraud in the Medicare Advantage program, such as marketing fraud and the improper adjustment of diagnostic codes to wrongfully inflate payments

The Numbers: Summary of Civil and Criminal Settlements and Judgments

Civil. In the first half of 2023, the healthcare industry collectively paid more than \$1 billion to settle alleged civil fraud matters. Additionally, several entities entered into corporate integrity agreements (CIAs), which permit the government to monitor future compliance. Ten individuals were excluded from participating in the federal healthcare programs.



CIVIL FCA RECOVERIES, CIAs, & EXCLUSIONS

		# of Recoveries:	Total Recovery:	Average Recovery:	CIAs	Exclusions
	Hospital & Health Systems	11	\$262,039,223	\$23,821,747	0	0
	Pharmaceutical Companies & Pharmacies	4	\$28,063,246	\$7,015,811	1	0
	Med Device/DME	7	\$580,272,508	\$82,896,215	1	0
	Individual Providers & Practice Groups	8	\$121,001,208	\$15,125,151	1	3
	Laboratory Services	3	\$28,740,620	\$9,580,206	1	0
	Home Health Services	3	\$11,168,000	\$3,722,666	0	7
	Long-term Care Providers	2	\$7,285,000	\$3,642,500	1	0
	Data Privacy	1	\$293,771	\$293,711	0	0

Notably, the government's fiscal year (Oct. 1, 2022–Sept. 30, 2023) recently closed, with some early estimates showing that DOJ and relators' FCA recoveries increased nearly \$400 million in comparison to the prior fiscal year – for a total of roughly \$2.6 billion in FCA recoveries across industries. As noted in Barnes & Thornburg's prior coverage [here](#), FY 2022 marked the lowest amount of FCA recoveries in the last decade. The DOJ releases its official fiscal year statistics in early 2024, which will be covered in Barnes & Thornburg's 2023 Healthcare Enforcement & Compliance Annual Report.

Criminal. On the criminal side, in the first half of 2023, 24 individuals and entities were convicted of healthcare fraud, primarily pharmaceutical companies and pharmacies, medical device and durable medical equipment companies, individual providers and practice groups, and laboratories. Sentences ranged from deferred prosecution to 25 years in prison; the convicted also were ordered to pay millions of dollars in restitution.

24

individuals and
entities convicted

Data Privacy, Cybersecurity & Access. HHS' Office for Civil Rights, which investigates violations of the Health Insurance Portability and Accountability Act (HIPAA), continued its rigorous enforcement and secured seven settlements (amounting to over \$1.9 million) with healthcare entities for alleged privacy and security violations. The Federal Trade Commission (FTC) also weighed in – announcing that the privacy of health data is a new priority for the agency. The FTC took enforcement action against four companies for unauthorized disclosure of patient health information and deceiving consumers. This is the first time the agency has enforced its health breach notification rule and the first time it returned funds to consumers whose health data was compromised.

\$1.9M

secured
settlements

Noteworthy Government Policy Updates & Case Law Developments

The government and courts were especially active in the first six months of 2023. Important developments include:

The United States Supreme Court. The Supreme Court issued two significant FCA decisions in summer 2023. In consolidated cases [U.S. ex rel. Schutte v. SuperValu Inc. and U.S. ex rel. Proctor v. Safeway, Inc.](#), the Court ruled that a defendant's subjective belief is paramount in determining whether the defendant had intent or knowledge of wrongdoing, known as scienter. This ruling will likely result in more fact-intensive, intrusive inquiries into defendants' activities, internal communications, and submission of claims for reimbursement. In [U.S. ex rel. Polansky v. Executive Health Resources, Inc.](#), the Court adopted a deferential standard of review for government motions to dismiss FCA claims, which may make it easier for the government to discharge whistleblower lawsuits that, among other things, lack merit, duplicate a pre-existing investigation, interfere in agency policies, or unduly waste government resources.

DOJ Policy Updates. The DOJ fine-tuned its enforcement policies to further promote compliance, including adding incentives, such as fine reductions and declinations of prosecution, to encourage entities to voluntarily self-disclose potential misconduct and cooperate with government investigations.

HHS-OIG Initiatives. HHS-OIG has continued to prioritize investigations into fraud against federal healthcare programs and has begun to update its industry-specific compliance program guidance. On Nov. 6, HHS-OIG released its General Compliance Program Guidance. The Guidance spans 91 pages and provides a general compliance framework for federal healthcare program providers and suppliers. This is the first major update to HHS-OIG's compliance program guidance materials in 15 years.

Conclusion

It is clear that the healthcare industry is, and will continue to be, a primary enforcement area for the government and a place of scrutiny by whistleblowers incentivized by a share in the recovery.

Stakeholders need to be vigilant in their understanding of the ever-evolving laws and rules and ensure that their compliance programs are up to date.

For more information about these developments, please refer to our [2023 Healthcare Enforcement and Compliance Mid-Year Report](#), contact the Barnes & Thornburg attorney with whom you work or John Kelly at 202-831-6731 or john.kelly@btlaw.com or Jacquelyn Papish at 202-831-6732 or jackie.papish@btlaw.com.



**BARNES &
THORNBURG** LLP