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# ***Health Law Regulatory and Compliance 2025 Update: What's Happened and What's Ahead?***

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# CLE Information

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# Agenda

Evolving Enforcement Landscape

Emerging Trends in Health Care Regulation

Focus on DEI

Insight from the Courts

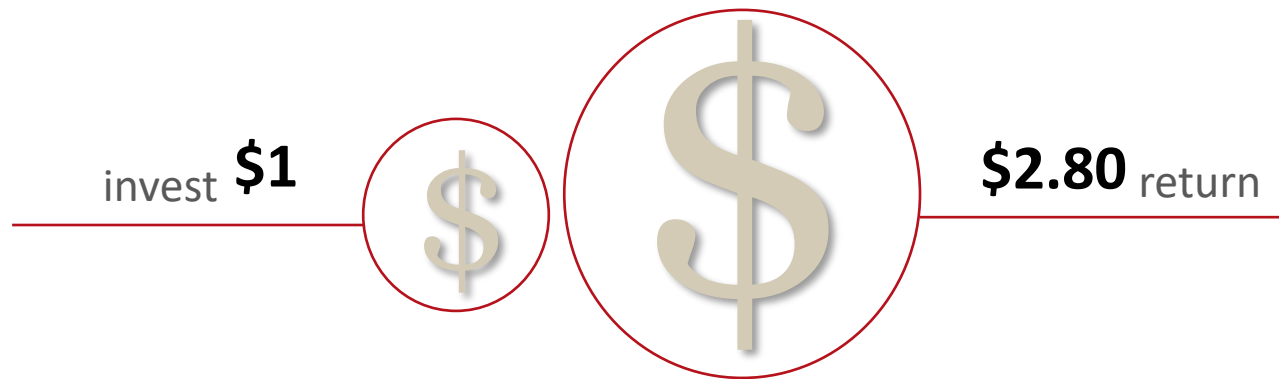




# Evolving Enforcement Landscape

# Government Focus on Fraud

Prosecuting “fraud” is good business

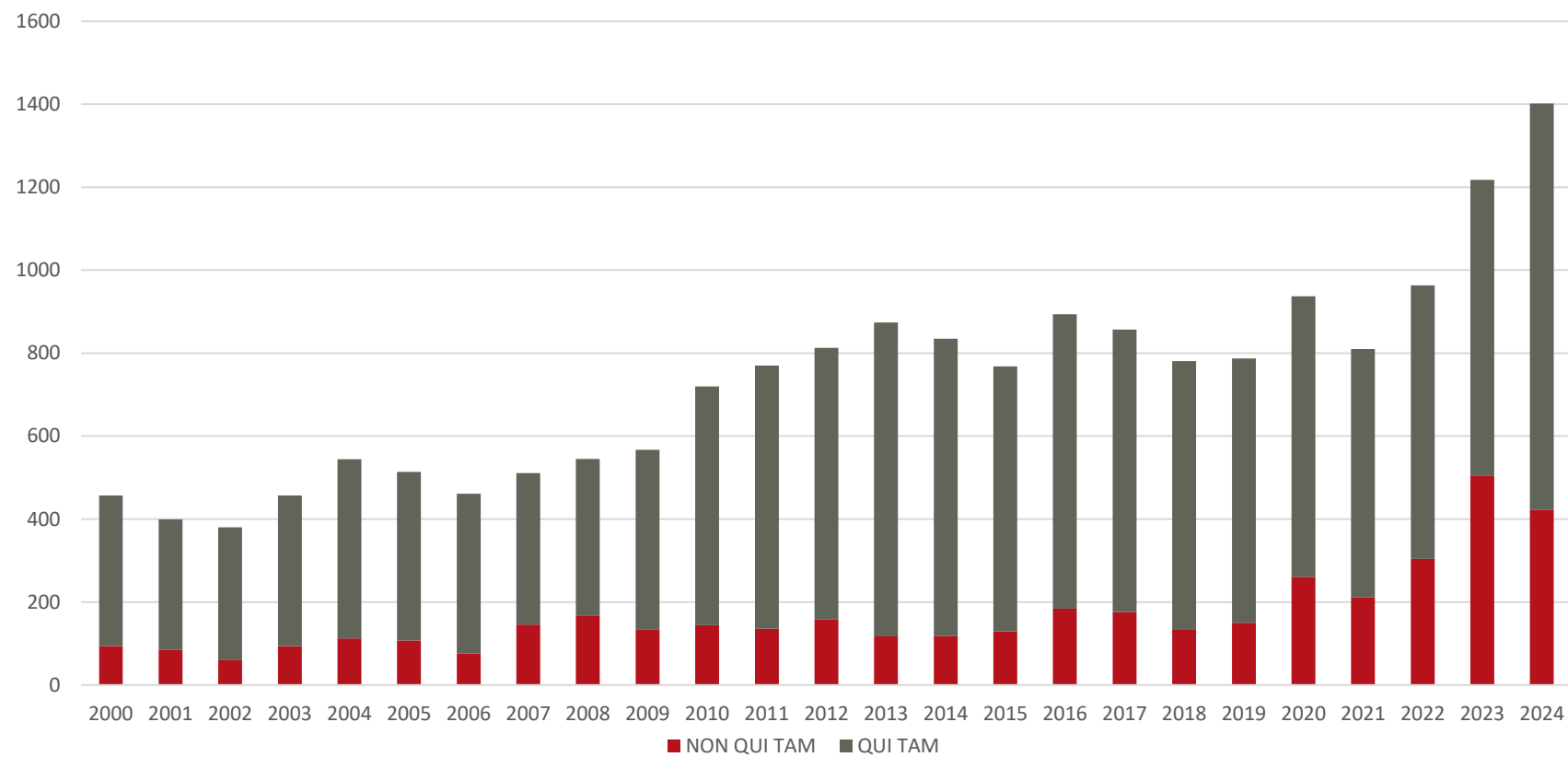


The Annual Report of the Departments of Health and Human Services and Justice stated that for every \$1 invested in OIG, DOJ and FBI investigations related to health care fraud in the past three years, \$2.80 was returned.

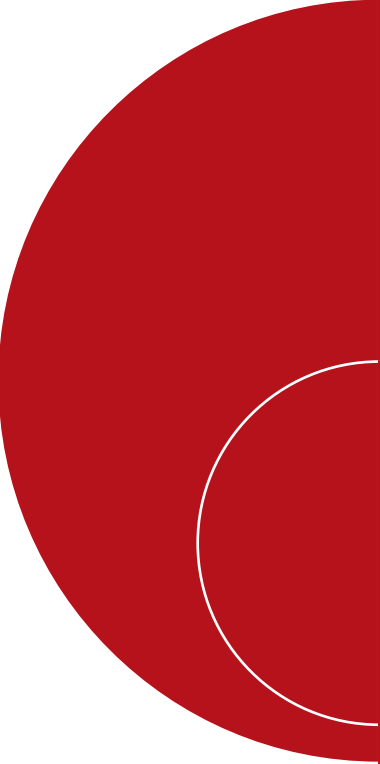


# Enforcement Updates

Number of New FCA Actions FY 2024



# Enforcement Updates



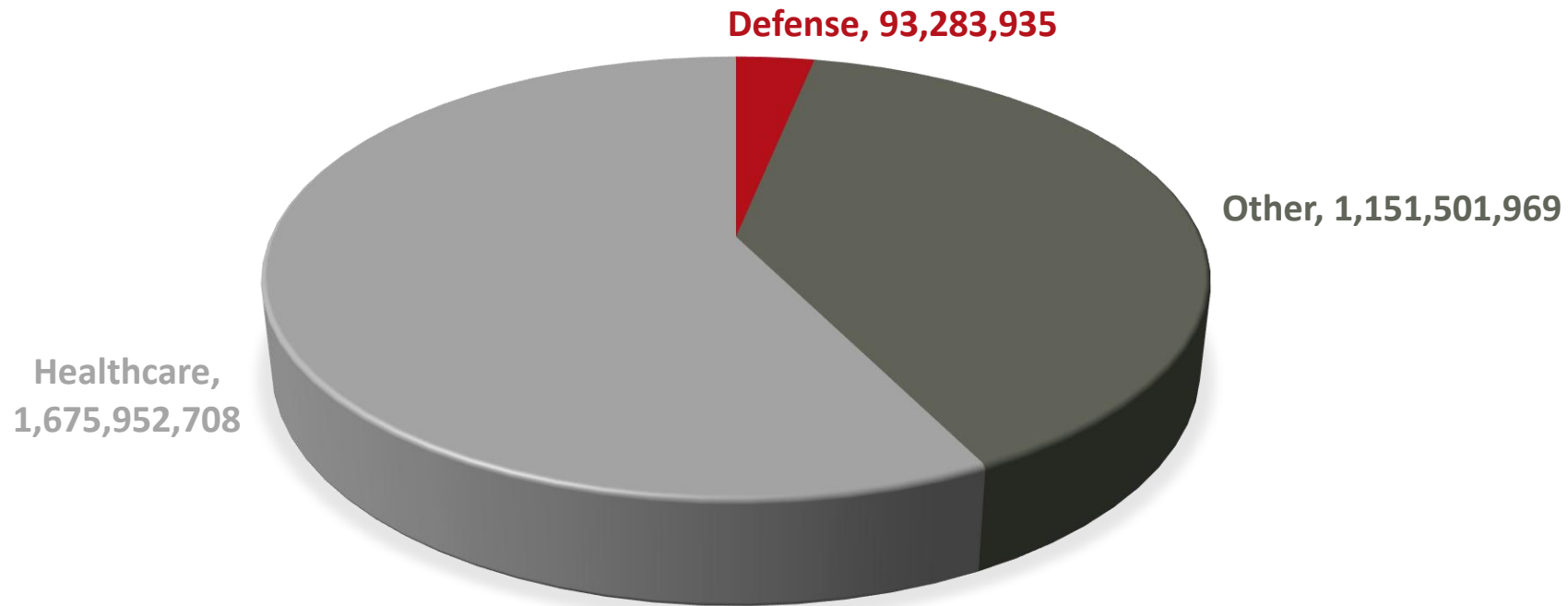
As of June 2025, FCA Recoveries:  
DOJ has secured ~ \$3.8 billion in  
judgments and settlements

Surpassing the \$2.9 B total from FY 2024

\*Final numbers may shift as post-trial briefing and appeals could alter damages/penalties




# Enforcement | 2024 FCA Recovery Breakdown

## FY 24 RECOVERIES





# Enforcement | 2024 Numbers

OIG's FY24 Efforts		
 <b>\$7.13B</b> Expected Recoveries/Receivables	 <b>1,548</b> Civil and Criminal Enforcement Actions	 <b>3,234</b> Excluded Individuals and Entities
Increase in recoveries from FY23's \$3.16B		

DOJ's FY24 False Claims Act Efforts		
<b>\$2.9B</b> FCA Recoveries	<b>979</b> New Qui Tam Cases Filed	<b>1,402</b> Total New Cases Fled
Slight increase in recoveries from FY23's \$2.78B 57% of FY24 recoveries related to health care cases		



# Enforcement | National Health Care Fraud Takedown

- On June 30, 2025, DOJ announced it was combating **\$14.6B** in alleged fraud through the 2025 Takedown.
  - 324 defendants criminally charged across 50 federal districts
  - Over **\$245M** in cash, luxury vehicles, and crypto currency seized
  - A total of **\$34.3M** in civil settlements from 106 defendants
  - Suspension or revocation of billing privileges for 205 providers
- ***Priorities:***
  - Telemedicine & Genetic Testing Fraud
  - Opioid Trafficking
  - DME Schemes
  - Fraudulent Wound Care

# Enforcement Trend | COVID-19

- **COVID-19 Fraud Enforcement Task Force**

- Established in 2021
- To date:
  - 3,500+ defendants charged
  - Over \$1.4 billion in CARES Act funds seized or forfeited
  - 400+ civil settlements and judgments
- Key Enforcement Areas:
  - Pathogen Panel Testing
  - Improper use of CARES Act funds
  - Improper use of PPP funds
  - Improper sale or distribution of COVID-19 OTC kit products



# Enforcement Trend | COVID-19

## *COVID-19 Criminal Enforcement*

- Lab CEO and Medical Director charged in \$500M scheme involving billing for COVID-19 tests never provided.
- Owner of Chicago laboratory convicted for participation in COVID-19 testing scheme. Sentenced to 7 years in prison; restitution and forfeiture of \$6.8M.

## *COVID-19 FCA Cases*

- **Urgent Care Company** paid \$3M to resolve FCA allegations of unnecessary strep & flu tests, inflating level of service rendered.
- **Doctor** paid \$3.5M to resolve FCA allegations related to COVID-19 Uninsured Program and E&M services not furnished.
- **Urgent Care Company** paid over \$12M to resolve FCA allegations regarding false claims for COVID-19 testing to the Uninsured Program for individuals who had health insurance.
- **Testing company** paid \$8M to resolve allegations of false claims submitted for COVID-19 testing under the Uninsured Program for individuals with health insurance.

## *COVID-19 Audits*

- Detailed in the June 2025 OIG report: 11 of 30 hospitals not in compliance with Provider Relief Fund requirements.
  - \$63M unallowable expenditure



# Enforcement Trend | Managed Care

- **Managed Care Marketing Practices**

- ***U.S. ex rel Shea v. eHealth, Inc.***, No. 21-cv-11777-DJC (D. Mass.)
  - DOJ intervened in qui tam action against three insurance companies, alleging they paid hundreds of millions of dollars in illegal kickbacks to defendant brokers in exchange for enrollments into their MA plans.
  - Defendant brokers allegedly directed Medicare beneficiaries to the plans based on the kickbacks rather than the suitability of the MA plans for the beneficiaries.
  - Illegal payments allegedly disguised as “marketing” or “sponsorship payments.”
  - Additional allegations against two of the insurance companies that they conspired with the broker defendants to discriminate against beneficiaries with disabilities because they were deemed to be less profitable.

# Enforcement Trend | Managed Care

- **Managed Care Risk Adjustment Practices**

- **December 2024: Health Association**

- Agreed to pay up to \$98M to settle allegation that it submitted invalid diagnosis codes to increase risk adjustment payment.

- **March 2025: Medical Group**

- Agree to pay \$62M to resolve allegations of improperly inflated MA payments resulting from falsely submitted diagnosis codes.

- **Other Developments**

- ***U.S. ex rel. Poehling v. UnitedHealth Group, Inc.***: Recommendation to grant United's motion for summary judgment in risk adjustment fraud case due to government's case being "devoid of evidence."
    - **September 2024 OIG Report Findings**: Three of the largest MAOs exaggerated severity of MA members' illness to increase risk adjustment payments.
    - **CMS** announcement of MA plan audits for Payment Years 2018 to 2024.



# Enforcement Trend | Lab Testing

*“Laboratory testing is an essential part of patient care, not a vehicle for greed and exploitation.”*

- **January 2025: Toxicology laboratory**

- \$4.4M settlement to resolve FCA allegations related to causing physicians to order medically unnecessary urine drug testing and hormone testing.

- **September 2025: Diagnostics laboratory**

- Former CEO agreed to pay \$4.25M to resolve FCA allegations of illegal payments to doctors for lab referrals disguised as consulting fees, processing and handling fees, and waivers of copayments and deductibles. Two doctors and 7 marketers also settled to resolve allegations of their involvement in the arrangement, totaling \$6M combined.

# Enforcement | On the Horizon



**Remote Patient Monitoring**

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**Skin Substitutes**

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**Civil Rights Fraud: DEI**

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# Updated Guidance and Emerging Trends in Health Care Regulation

# Updates | 60-Day Rule

- **Statutory Overview:**

- Providers, suppliers, Medicaid MCOs, MAOs, and PDP sponsors that received an overpayment must report and return payment, providing notice of the reason for the overpayment to the agency or appropriate contractor.
  - Overpayment is defined as “any funds that a person receives or retains under Title XVIII (Medicare) or Title XIX (Medicaid) to which the person, after applicable reconciliation, is not entitled under such title.”
- **Deadline for Reporting & Returning:**
  - 60 days after the overpayment was identified for claims; or
  - The date any corresponding cost report is due, if applicable.

- **New Regulations effective January 1, 2025**

# Updates | 60-Day Rule

- **What Changed:**

- **Identification:**

- Updated rule eliminated the reasonable diligence and quantification standards and replaced them with the FCA definitional standards.
    - An overpayment is identified if a provider or supplier **has actual knowledge, acts in deliberate ignorance, or acts in reckless disregard of the overpayment.**

- **Quantification:**

- Previously, an overpayment was considered “identified” when a provider determined, or should have determined through reasonable diligence, that an overpayment was received, and the amount was quantified.
    - Under the updated rule, the obligation to report and return an overpayment **begins upon identification, even if the exact amount is undetermined.** In other words, the 60-day clock to report and return overpayments begins immediately, despite incomplete quantification.

- **Suspension:**

- Updated rule allows a **180-day suspension** of the reporting obligation if a Medicare participant identifies an overpayment and conducts a timely, good faith investigation.



# Updates | Joint FCA Working Group

- On July 2, 2025, DOJ and HHS announced formation of a new Joint False Claims Act Working Group.
  - Group will seek to maximize cross-agency collaboration.
    - Target traditional areas such as Medicare Advantage fraud, kickbacks, and drug device pricing practices.
    - Expand into new enforcement areas such as network adequacy requirements, defective medical devices, and manipulation of EMR system to drive inappropriate utilization.



# Updates | Bondi Memo



Office of the Attorney General  
Washington, D. C. 20530

- On February 5, 2025, Attorney General Pam Bondi issued a memo addressing the use of subregulatory guidance in enforcement actions.
- The memo rescinds the 2021 Garland Memo and reinstates the Sessions Memo.
- *“Guidance documents violate the law when they are issued without undergoing the rulemaking process established by law yet purport to have a direct effect on the rights and obligations of private parties governed by the agency or otherwise act as a substitute for rulemaking.”*
  - Consider: LCDs, Manuals, FAQs



# Updates | DOJ Criminal Enforcement Priorities

**A May 12, 2025, Criminal Division Memo identified 10 criminal enforcement priorities:**

1. Waste, fraud and abuse;
2. Trade and customs fraud, including tariff evasion;
3. Market manipulation, especially if perpetrated by or through Chinese affiliated companies listed on U.S. exchanges;
4. Investment fraud;
5. Sanctions violations;
6. Money laundering offenses;
7. Material support by corporations to foreign terrorist organizations;
8. Unlawful manufacturing or distribution of narcotics and opioids;
9. Bribery that impacts U.S. national interests, undermines U.S. national security, harms the competitiveness of U.S. businesses, or enriches foreign corrupt officials; and
10. Crimes involving digital assets, including investor or consumer fraud and the use of digital assets in furtherance of criminal activity.

# Updates | DOJ Civil Enforcement Priorities

**A June 11, 2025, Civil Enforcement Memo identified 5 enforcement priorities:**

**1. Combatting Discriminator Practices and Policies**

- *“The Civil Division will use all available resources to pursue affirmative litigation combatting unlawful discriminatory practices.”*
- *“In particular, the [Division] is authorized to bring suit under the [FCA] . . . against . . . entities that receive federal funds but knowingly violate civil rights law.”*

**2. Ending Antisemitism**

- *“The Civil Division will prioritize investigations and enforcement actions against entities that make claims for federal funds but knowingly violate federal civil rights laws by participating in or allowing antisemitism.”*

**3. Protecting Women and Children**

- *“Pursue investigations under the False Claims Act of false claims submitted to federal health care programs for any non-covered services related to radical gender experimentation.”*
- *“The Civil Division will aggressively pursue claims under the False Claims Act against health care providers that bill the federal government for impermissible services. This includes, for example, providers that attempt to evade state bans on gender dysphoria treatments by knowingly submitting claims to Medicaid with false diagnosis codes.”*

**4. Ending Sanctuary Jurisdictions**

**5. Prioritizing Denaturalization**



# Medicaid: Undocumented Immigrants

- CMS is increasing its financial oversight of federal Medicaid dollars with a particular focus on funds spent on the nonemergent care of undocumented immigrants.
- The agency informed states that it would “be conducting focused reviews of each state’s Medicaid expenditures and in-depth financial management reviews.”
- If the review identifies federal funds that were spent improperly, CMS will seek recoupment of that money.
- Additionally, CMS will review Medicaid coverage eligibility requirements and will seek “to close any loopholes and strengthen enforcement.”

# Artificial Intelligence

## AI Applications

### Health Care Providers

- Eligibility verification
- Predictive analytics for patient care
- Workflow automation

### DOJ

- Detecting fraud, waste, and abuse through data analytics

## Compliance Risks & Oversight

### Key Risks:

- Bias
- Data Privacy
- Regulatory Noncompliance

### Governance Measures:

- Define approved AI use cases
- Implement patient consent procedures
- Ensure clinician oversight
- Monitor and mitigate bias
- Establish ongoing compliance policy

# Government Enforcement of AI

## FCA Enforcement Considerations:

- FCA:
  - False Claim
  - Knowingly Submitted
  - That is Material
- AI **may not** show intent, but entities still liable for reckless disregard in monitoring
- Risk rises when AI tools are unmonitored

## Notable Enforcement Examples:

- **Hospital system:** \$23M settlement for automatically coded ER claims
- **Health system:** \$1.4M criminal penalty for AI automation fraudulently enrolling Medicare beneficiaries

## Compliance Considerations

- Implement and enforce AI governance policies
- Ensure continuous monitoring of AI tools
- Train staff on proper AI use and oversight
- Maintain accountability for all AI-generated outputs



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# Focus on DEI

# Students for Fair Admissions

Eliminating racial discrimination means eliminating all of it. And the Equal Protection Clause, we have accordingly held, applies “without regard to any differences of race, of color, or of nationality”—it is “universal in [its] application.”

For the reasons provided above, the Harvard and UNC admissions programs cannot be reconciled with the guarantees of the Equal Protection Clause. Both programs lack sufficiently focused and measurable objectives warranting the use of race, unavoidably employ race in a negative manner, involve racial stereotyping, and lack meaningful end points. We have never permitted admissions programs to work in that way, and we will not do so today.

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# Executive Order 14173

Sec. 2. Policy. It is the policy of the United States to protect the civil rights of all Americans and to promote individual initiative, excellence, and hard work. I therefore order all executive departments and agencies (agencies) to terminate all discriminatory and illegal preferences, mandates, policies, programs, activities, guidance, regulations, enforcement actions, consent orders, and requirements. I further order all agencies to enforce our longstanding civil-rights laws and to combat illegal private-sector DEI preferences, mandates, policies, programs, and activities.

# Health Care Targets of DEI Complaints

Target	Complainant	Date Filed	Agency	Description of Discriminatory Claims
Health System	Wisconsin Institute for Law and Liberty (WILL) / Do No Harm (DNH)	8/14/2024	HHS OCR	Minority Stroke and Minority Men's Health Center Programs
Children's Hospital	WILL / DNH	12/17/2024	HHS OCR	Scholarship, research internship, and administrative fellowship programs
University School of Medicine	WILL / DNH	1/15/2025	HHS OCR	Medical education, training, and scholarship programs
University Medical Center	Consumer's Research	3/18/2025	HHS OCR	Recruitment practices, use of research grants, clinical trial programming, and training curriculum
University Health System	DNH	3/19/2025	HHS OCR	Recruitment practices, pipeline and enrichment programs, scholarship and financial aid, and training curriculum
College of Health Sciences	DNH	3/19/2025	HHS OCR	Recruitment practices, pipeline and enrichment programs, and training curriculum
Health System	America First Legal (AFL)	4/28/2025	HHS OCR	Organ transplant program, employment decisions, medical education, and supply chain
Health System	AFL	5/6/2025	MI AG	Organ transplant program, employment decisions, medical education, and supply chain



# Civil Rights Laws + False Claims Act

May 19, 2025



U.S. Department of Justice  
Office of the Deputy Attorney General

The Deputy Attorney General

MEMORANDUM

FROM:

SUBJECT:

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The False Claims Act is also implicated whenever federal-funding recipients or contractors certify compliance with civil rights laws while knowingly engaging in racist preferences, mandates, policies, programs, and activities, including through diversity, equity, and inclusion (DEI) programs that assign benefits or burdens on race, ethnicity, or national origin. While racial discrimination has always been illegal, the prohibition on such policies became clear after the Supreme Court stated that “[e]liminating racial discrimination means eliminating all of it.” *Students for Fair Admissions, Inc. v. President & Fellows of Harv. Coll.*, 600 U.S. 181, 205 (2023).

The Department recognizes that it alone cannot identify every instance of civil rights fraud. Congress likewise has recognized as much and, as a result, has authorized private parties to protect the public interest by filing lawsuits and litigating claims under the False Claims Act—and, if successful, sharing in any monetary recovery. *See* 31 U.S.C. § 3730. The Department strongly encourages these lawsuits. The Department also encourages anyone with knowledge of

# FCA Risk Related to DEI Initiatives

- **Falsity:**

- To become a Medicare provider, or when undergoing a change of ownership, entities must attest to compliance with Title VI of the Civil Rights Act of 1964
- Other federal funding, like FEMA and NIH grants, require attestations of compliance with civil rights laws
- To comply with EO 14173, CMS may change 855A and 1500 forms to require attestations regarding civil rights laws

- **Knowingly (scienter):**

- Subjective belief: actual knowledge, deliberate ignorance of the truth or falsity, or reckless disregard of the truth or falsity

- **Materiality:**

- Going forward, EO 14173 requires government contractors to admit that compliance with anti-discrimination laws is material to the government's decision to pay



# Trump Administration Freezes \$108M in Funding for Duke Health

- Investigation by Department of Education's Office for Civil Rights (DOE OCR)
- Freeze targets research funding for Duke University School of Medicine and the overall university.
- Allegations: racial preferences in hiring, student admissions, selection onto law journals, governance, patient care, and other operations.
- Letter from HHS and DOE asking Duke to review policies for illegal use of race preferences and create a Merit and Civil Rights Committee to work with the federal government.
- Duke has largely remained silent during the investigation.



# NIH Grants Canceled

- Consolidated civil actions filed in Massachusetts federal court to restore hundreds of grants worth more than \$1 billion that NIH canceled as allegedly illegal and discriminatory.
- Terminated grants funded research for studies on race and gender identity, mitigating kidney disease, Alzheimer's disease and cervical cancer in diverse populations, climate change, and vaccine hesitancy.
- In June, the district court granted summary judgment to the plaintiffs finding that the grant terminations were arbitrary and capricious.
- On August 21, the Supreme Court stayed the district court's injunction against the cancelations and remanded to the First Circuit.



# Civil Rights Laws + False Claims Act



Office of the Attorney General  
Washington, D. C. 20530

July 29, 2025

## MEMORANDUM FOR ALL FEDERAL AGENCIES

FROM: THE ATTORNEY GENERAL  
SUBJECT: GUIDANCE FOR RECIPIENTS OF FEDERAL FUNDS REGARDING UNLAWFUL DISCRIMINATION

### I. INTRODUCTION

One of our Nation's bedrock principles is that only is discrimination based on protected characteristics dangerous, demeaning, and immoral. Yet in recent years, eye toward, or even encouraged, various discriminatory practices purportedly benign labels, objectives, or intent government will not stand by while recipients of federal funds

This guidance clarifies the application of initiatives that may involve discriminatory practices and Inclusion ("DEI") programs.<sup>1</sup> Entities receiving federal antidiscrimination laws, must ensure that they do not discriminate on the basis of race, sex, color, or national origin. of that requirement, this guidance identifies "Best practices" entities comply with federal antidiscrimination laws, but rather practical recommendations.

Entities that receive federal financial assistance must ensure they are not in violation of antidiscrimination laws, including educational institutions and private employers, should review this guidance carefully to ensure all programs comply with their legal obligations.

<sup>1</sup> DEI programs go by other names as well, such as Diversity, Equity, Inclusion, and Accessibility ("DEIA") and Diversity, Equity, Inclusion, and Belonging ("DEIB").

### II. EXECUTIVE SUMMARY

This guidance emphasizes the significant legal risks of initiatives that involve discrimination based on protected characteristics and provides non-binding best practices to help entities avoid the risk of violations. Key points include:

- **Statutory nondiscrimination requirements:** Federal law prohibits discrimination based on protected characteristics like race, sex, color, national origin, or religion.
- **Legal pitfalls of DEI Programs:** The use of terms such as "DEI," "Equity," or other euphemistic terms does not excuse unlawful discrimination or absolve parties from scrutiny regarding potential violations.

# DOJ Best Practices

- Ensure inclusive access: e.g., no race-based scholarships, internships, hiring initiatives
- Focus on skills and qualifications
- Prohibit demographic-driven criteria
- Document legitimate rationales
- Scrutinize neutral criteria for proxy effects like socioeconomic status, first-generation status, geographic diversity
- Eliminate diversity quotas and “diverse slate” requirements
- Avoid exclusionary training programs
- Include nondiscriminatory clauses in contracts to 3rd parties and monitor compliance
- Establish or reinforce clear anti-retaliation procedures and create reporting mechanisms



# Practical Guidance

- Evaluate your organization's website, internal communications, trainings, and policies to ensure they do not violate the law.
- Review descriptions of any teams and positions that are associated with or work on DEI initiatives.
- Assess recruitment, hiring, and promotion policies, procedures, forms, and templates
  - Avoid race, sex, and "loaded" application questions
  - Analyze use of criteria related to socioeconomic status, first-generation-status, geographic diversity
  - Prioritize use of universally applicable criteria (e.g., financial hardship)
  - Consistently apply and document rationales for criteria
- Review any programs that consider race, gender, or sex in selection, and update selection.
- Avoid using language that may violate the law or trigger scrutiny.
  - Diversity, accessibility, inclusion and belonging, DEIA, DEIB, cultural competence, lived experience, transgender issues, vaccine hesitancy, opportunities for underprivileged communities





# Insight from the Courts



# Court Cases| Qui Tam Constitutional Challenges

## **U.S. ex rel. Polansky v. Exec. Health Res., Inc.**

*599 U.S. 419 (2023)*

- In dissent, Justice Thomas raised “serious constitutional questions” regarding the qui tam provisions of the FCA, including their potential inconsistency with Article II. Justices Kavanaugh and Barrett shared same concern in concurrence.

## **U.S. ex rel. Zafirov v. Florida Medical Associates**

*2024 WL 4349242 (M.D. Fla. Sept. 30, 2024)*

- Court adopted the reasoning from the Thomas dissent in Polansky and held that the qui tam provisions of the FCA violated Article II and the Appointments Clause.
  - Appealed to 11th Circuit.

## **Recent Challenge**

*Penelow, et al. v. Janssen Prods. LP, No. 12-cv-7758, 2025 WL 342079 (D.N.J. Jan. 30, 2025).*

- Pharmaceutical company filed a constitutional challenge to the FCA qui tam provisions in its appeal to the Third Circuit of a \$1.6B judgment related to illegal promotion of HIV medications.

# Court Cases| Qui Tam Constitutional Challenges

- July 28, 2025, the U.S. District Court for the Southern District of Ohio certified for interlocutory appeal to the U.S. Court of Appeals for the Sixth Circuit the question of whether the False Claims Act's qui tam provisions violate Article II of the Constitution.
  - The twin orders were issued in two cases by Judge Douglas Russell Cole, a 2019 Trump appointee.
- The fact that the district court certified the question for interlocutory appeal does not necessarily mean the Sixth Circuit will hear it.

*In re Trihealth, Inc., et al.* (Case No. 25-0306); *In re Trihealth, Inc., et al.* (Case No. 25-0307).

# Court Cases | Supervalu & the Aftermath

- In Supervalu, the Supreme Court rejected the objective reasonableness test for determining scienter under the FCA.
- In the aftermath of Supervalu, it has been more difficult for defendants to use the FCA scienter requirement as a basis for dismissal.
  - Defendant's subjective intent is key, and this creates a question of fact.

*United States ex rel. Streck v. Eli Lilly and Co.*, 2025 WL 2618821 (7th Cir. Sept. 11, 2025).

*Island Indus., Inc. v. Sigma Corp.*, 2025 WL 2422455 (9th Cir. Aug. 21, 2025).

*United States ex rel. Behnke v. CVS Caremark Corp.*, 2025 WL 1758623 (E.D. Pa. June 25, 2025)

# Court Cases | Understanding FCA Materiality

## **United States ex rel. Wheeler v. Acadia Healthcare Co.**

127 F.4th 472 (4th Cir. 2025)

- 4th Circuit reversed the district court's dismissal, holding that Acadia's failure to provide therapy and counseling to patients in addiction treatment program was material to the government's decision to pay.

## **United States ex rel. Montcrief v. Peripheral Vascular Assocs.**

133 F.4th 395 (5th Cir. 2025)

- Affirmed jury verdict on grounds that materiality finding was supported by evidence at trial that Medicare would not have paid the relevant claims if it had known it was being billed for incomplete procedures.
- Affirmed the district court decision, declining to extend FCA's scienter requirement to the materiality element in express certification case.



# Court Cases| Understanding FCA Materiality

## **United States ex rel. Behnke v. CVS Caremark Corp.**

2025 WL 1758623 (E.D. Pa. June 25, 2025)

- District court ruled that CVS (acting as a PBM) inflated drug prices; applying Escobar, court found the misrepresented drug prices were material.
- If CMS had known of Caremark's guaranteed average price terms and the discrepancy with reported prices, this would have likely affected CMS's decision to pay.
  - \$95M in overcharges trebled to \$285M with civil penalties of \$4.9M

## **United States ex rel. Streck v. Eli Lilly and Co.**

2025 WL 2618821 (7th Cir. Sept. 11, 2025).

- Seventh Circuit affirmed jury verdict finding that Eli Lilly violated the FCA by reporting falsely deflated drug prices to the government.
- Addressing materiality: "Noncompliance with the law resulting in large price differentials in how much the government owes 'offers strong support for a finding of materiality.'"

# Court Cases | FCA Excessive Fines

## United States ex rel. Bassan v. Omnicare

2025 WL 1865202 (S.D.N.Y. July 07, 2025)

- Defendant convicted by jury for improperly billing for invalid subscriptions, damages of approximately **\$136M**.
- Trebled to roughly **\$407M**.
- Also civil penalties per false claim. Government sought and received 4:1 ratio, equaling **\$542M**.
  - “[T]he amount sought by the Government – is probably the outer limit of what can be constitutionally condoned in a case like this one, where actual damages are substantial.”

## United States ex rel. Taylor Healthcare Assocs. of Texas

2025 WL 624493 (N.D. Tex. Feb. 26, 2025)

- Jury found Defendant liable for submitting 21,844 false claims.
- Actual damages of **\$2.8M**
- Relator sought judgment for **\$8.3M** in trebled damages and **\$450M** in Civil Penalties
- Court concluded that the FCA's civil penalty, as applied in this case, constituted an excessive fine and instead imposed a reduced penalty equal to three times actual damages.

# Court Cases | AKS “Willfulness”

## United States ex rel. Hart v. McKesson Corp.

96 F.4th 145 (2d Cir. 2024)

- Relator alleged that McKesson provided two business management tools to its customers without charge in exchange for those customers’ commitments to purchase drugs from McKesson.
- District Court dismissed FCA claims because relator failed to allege sufficient facts to suggest McKesson acted “willfully” as required by AKS.
- Second Circuit affirmed: “‘willfully’ in the AKS means ... with a ‘bad purpose.’ .... In other words, ‘with knowledge that his conduct was unlawful.’”

# Court Cases| **AKS “Inducing Referrals”**

## **United States. v. Sorensen**

**134 F.4th 493 (7th Cir. 2025)**

- Sorensen owned DME company, which collaborated with marketing firms and a manufacturer to advertise and promote orthopedic braces. Interested patients provided their information in response to advertisements. This information was used to generate prefilled, unsigned prescription forms sent to patients’ physicians. Physicians retained full discretion to sign and return the forms.
- Court reversed Sorensen’s conviction, finding insufficient evidence that Sorensen’s payments to marketing firms constituted illegal kickbacks.
- The marketers were not “physicians in a position to refer their patients nor other decisionmakers in positions to ‘leverage fluid, informal power and influence’ over healthcare decisions.”



# Notable Enforcement Actions for 2025

DATE	SUMMARY	PENALTY
1/3/2025	A drug testing lab and two individuals agreed to pay \$4.4 M to settle FCA claims that they caused physicians to submit unnecessary urine drug and hormone tests to Medicare.	\$4.4 M
1/16/2025	A pharmaceutical company paid \$59.7 M to settle FCA and AKS claims that its subsidiary provided improper speaker fees and meals to induce its migraine drug prescriptions.	\$59.7 M
1/31/2025	A Florida health care company agreed to pay up to \$4.9 M to settle FCA and AKS claims that it improperly paid a marketing service for Medicare referrals.	\$4.9 M
3/14/2025	A health care provider paid \$58.74 M to settle claims of inflated Medicare Advantage billing for false spinal diagnoses, while its owner and an affiliated radiology group paid \$1.76 M and \$2.35 M for their roles in supporting the false claims.	\$62.85 M total
4/29/2025	A pharmaceutical manufacturer paid \$202M to settle FCA claims that it improperly compensated doctors with speaker fees and meals from 2011–2017 to induce HIV drug prescriptions.	\$202 M
5/22/2025	California-based Community Health System and Physician Network Advantage paid \$31.5 M to settle FCA claims that they provided financial incentives to physicians to use Epic EHR systems.	\$31.5 M
8/5/2025	Nita Almuete Paddit Palma of Glendale, CA, was sentenced to 9 years in federal prison and ordered to pay \$8.27 M for a \$10.6 M Medicare hospice fraud scheme, controlling two hospices despite prior Medicare exclusion.	9 years in prison; \$8.27 M

# Practical Takeaways

- Prepare for surging FCA enforcement
- Review DEI policies and initiatives
- Monitor AI and data use, implement governance policy and committee
- Revise and strengthen compliance programs as enforcement evolves

# Questions



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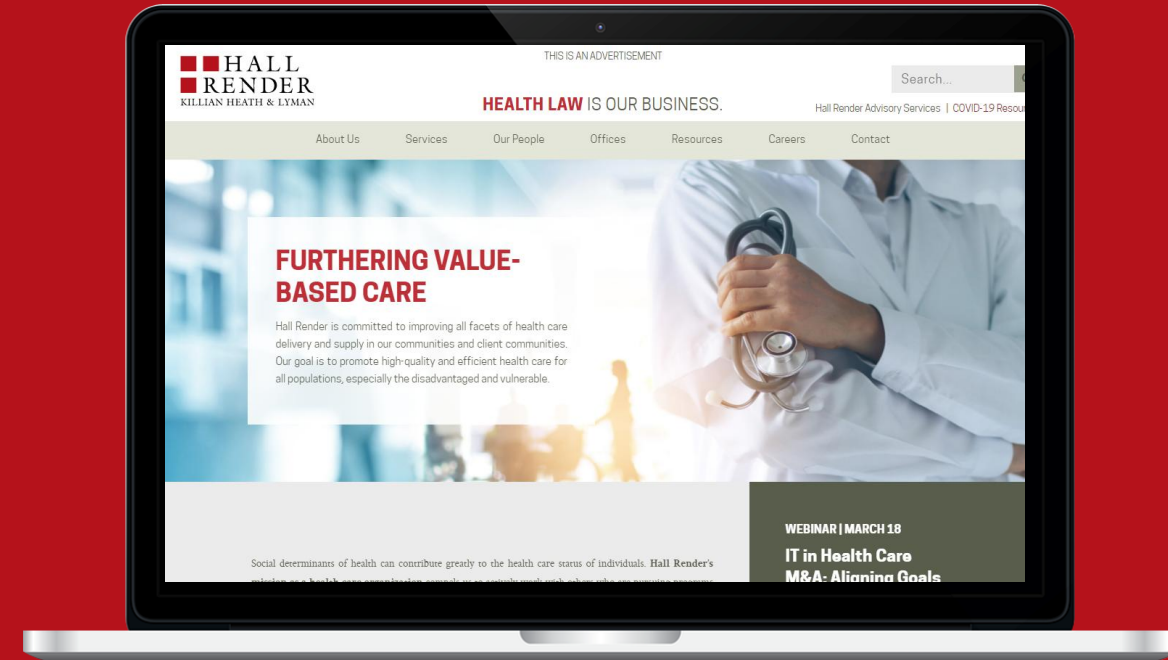
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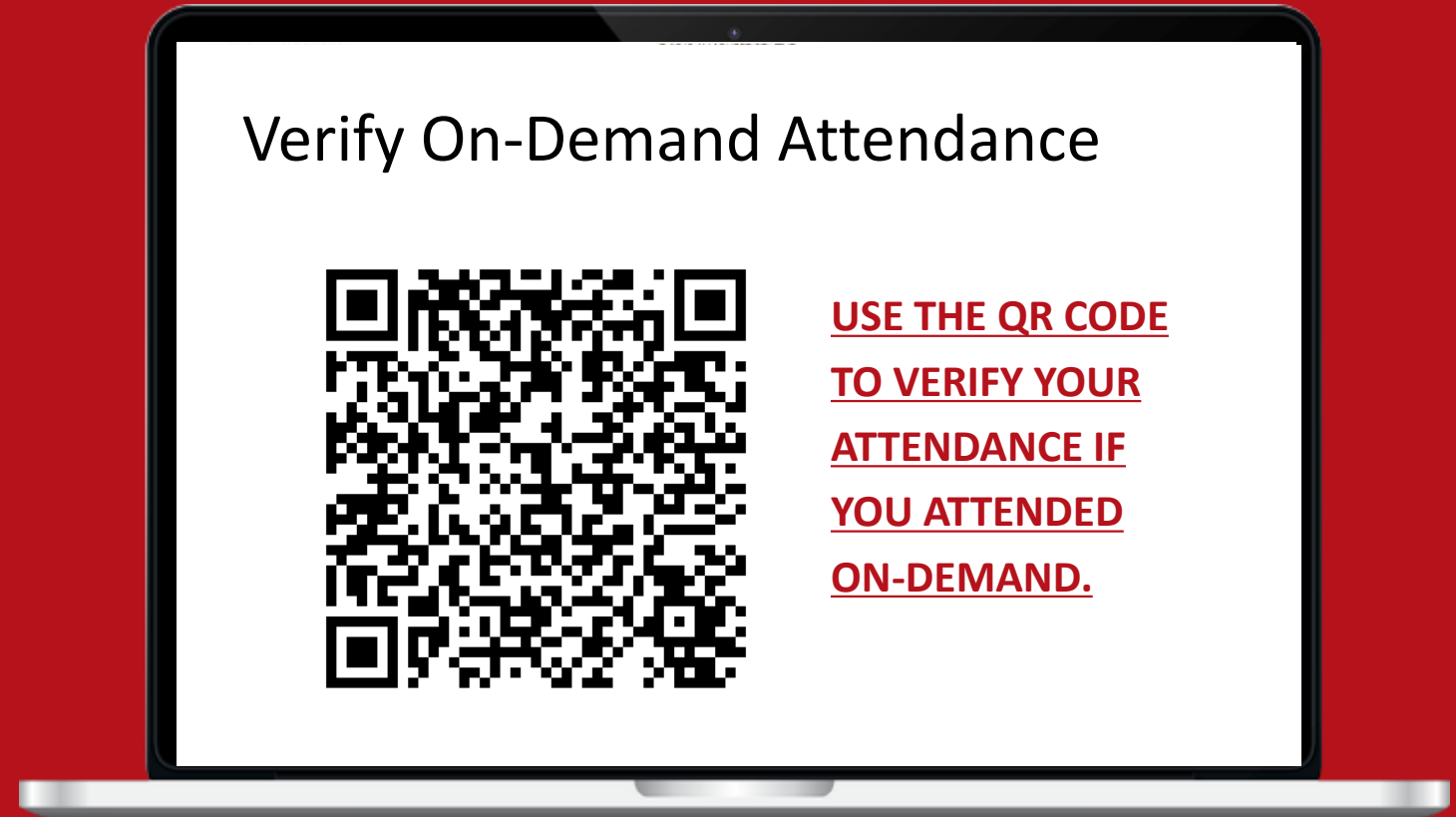
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