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PRACTICAL COUNSEL
VIRTUAL INSTITUTE

Enforcement Trends, Regulatory Updates, and What's New

Health Care Compliance 2026



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Agenda

- Evolving Enforcement Landscape
- Updated Guidance and Emerging Trends
- OIG FAQ Updates and EKRA Developments
- Insight from Court Cases
- Compliance in the 340B Program
- Focus on DEI
- Practical Takeaways
- Appendix:
  - Notable Settlements
  - Recent Fraud and Abuse Developments

Presenters



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Evolving Enforcement Landscape

Government Focus on Fraud

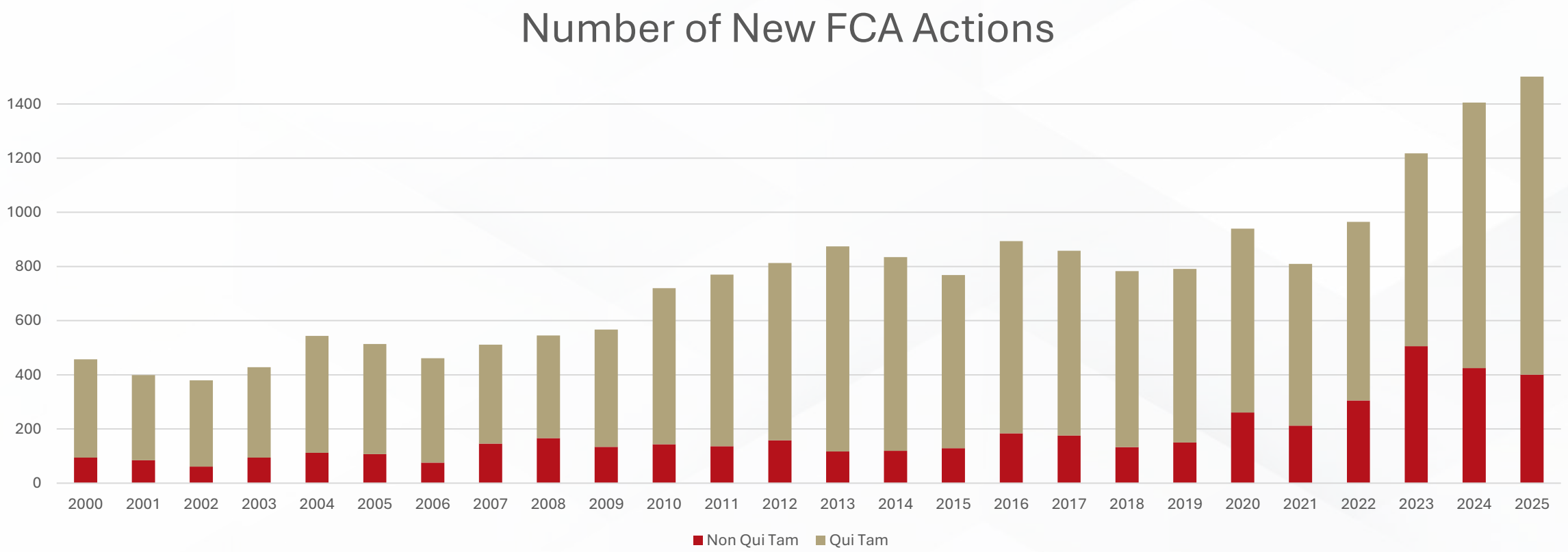
Prosecuting “fraud” is good business



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.

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Enforcement Updates | FCA Case Volume



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Notable Enforcement Actions for 2026

DATE	SUMMARY	PENALTY
1/3/2025	Drug testing lab and two individuals settled FCA claims; allegedly caused physicians to submit Medicare claims for unnecessary urine drug and hormone tests. Entered HHS-OIG integrity agreements.	$4.4M
1/16/2025	Pharmaceutical company settled FCA and AKS allegations; subsidiary allegedly used improper speaker fees and meals to induce migraine prescriptions.	$59.7M
1/31/2025	Florida health care company settled allegations of illegal marketing payments for Medicare beneficiary referrals, violating FCA and AKS.	Up to $4.9M
3/14/2025	Health care provider inflated Medicare Advantage reimbursements with false spinal enthesopathy and sacroiliitis codes; owner and affiliated radiology group paid $1.76M and $2.35M respectively.	$58.74M
4/29/2025	Pharmaceutical manufacturer resolved FCA allegations of improper remuneration (speaker programs and meals) to induce HIV drug prescriptions (2011–2017).	$202M
5/22/2025	Community Health System and Physician Network Advantage resolved FCA claims for providing financial benefits and EHR subsidies to physicians.	$31.5M
8/5/2025	Nita Almuete Paddit Palma sentenced to 9 years for a $10.6M Medicare hospice fraud scheme; controlled two hospices despite prior Medicare exclusion.	$8.27M restitution

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Enforcement Updates | FY 2025 Recoveries

As of June 2025, DOJ had secured approximately $3.8 billion in FCA judgments and settlements.

That figure already surpasses the $2.9 billion total recorded for FY 2024.

Final numbers may still change based on jury verdicts, post-trial briefing, and appeals.

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

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Enforcement | 2025 FCA Recovery Breakdown

Health care: $1,675,952,708

Other: $1,151,501,969

Defense: $93,283,935

Health care accounted for roughly 57% of all FY 2025 False Claims Act recoveries.

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Enforcement | 2024 Numbers

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OIG's FY24 Efforts

$7.13B Expected Recoveries/Receivables	**1,548** Civil and Criminal Enforcement Actions	**3,234** Excluded Individuals and Entities
Increase in recoveries from FY23's $3.16B		

DOJ's FY24 False Claims Act Efforts

$2.9B FCA Recoveries	**979** New Qui Tam Cases Filed	**1,402** Total New Cases Filed
Slight increase in recoveries from FY23's $2.78B; 57% of FY24 recoveries related to health care cases		

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Updated Guidance and Emerging Trends in Health Care Regulation

Enforcement Updates

Comprehensive Regulations to Uncover Suspicious Healthcare

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February 26, 2026 | CRUSH

- CMS RFI for CRUSH Rule
  - Agency seeking input on enhanced provider enrollment screening, identity proofing and ownership requirements, preclusion list reforms, laboratory testing fraud, DMEPOS supplier oversight, claim filing deadlines, AI-assisted coding, beneficiary solicitation protections, Medicaid and CHIP fraud …
  - **State AG Response (March 2026) (CA, CO, AZ, DE, IL, ME, MA, MI, MN, NJ, NV, NY, OR, VT, WA)**
    - Disagree that state Medicaid programs are overrun with “systemic” fraud or that fraud was recently “discovered”
    - Use broad deferrals or withholding of federal Medicaid funds sparingly

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Enforcement Updates

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Treasury Gets Involved

March 30, 2026 | FinCEN Advisory on Health Care Fraud Schemes

- Dep't of Treasury's Financial Crimes Enforcement Network (FinCEN) issued an advisory to financial institutions: "be vigilant in identifying and reporting suspicious transactions potentially related to health care fraud schemes ...."
- Dedicated webpage to confidentially accept whistleblower tips.

Enforcement Updates

CMS Medicaid Fraud War Room

April 2026 | Medicaid Fraud War Room

- CMS launched "bold new initiative created in direct collaboration with the White House Task Force to Eliminate Fraud led by Vice President JD Vance."
- Cross-functional strike force deploying advanced data analytics.
- War Room is leveraging the full arsenal of existing state and federal program integrity authorities, including provider exclusions, civil monetary penalties, and overpayment recovery, while helping states implement payment suspensions faster.
  - ***"CMS Medicaid Fraud War Room Stops More Than $203 Million in Improper Payments During First 88 Days"***



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Enforcement Updates

2025 SRDP Settlements

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April 2026

- CMS released data on its 2025 settlements of voluntary self-disclosures related to the Stark Law
  - Aggregate settlements under protocol since inception exceed $100M
    - Down from 314 settlements in 2024
  - **244 self-disclosure settlements** in 2025, totaling **over $20M**
  - Largest 2025 SRDP settlement: $2.68M
  - Individual settlements are not reported, but the **average settlement amount was $83,594 in 2025**

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Enforcement Updates

DOJ Fraud Oversight Through Careful Use of Statistics (FOCUS)

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April 30, 2026 | Focus Initiative

- New anti-fraud program designed to strengthen relationship with data-miner FCA whistleblowers.
- Since FY24, data miners have filed more than 45% of all qui tams.
- The initiative invites data miners to meet with the civil fraud section: how does data reliably signal patterns of fraudulent activity.
- The Department will prioritize data miners that have demonstrated an investment in pre-filing diligence and commitment to analytical rigor, familiarity with program rules, and legally sufficient allegations.

"Sophisticated data analytics have become an increasingly important means of identifying fraud trends and uncovering patterns of misconduct across federal programs . . . The FOCUS initiative reflects our commitment to ensuring that the Civil Division is engaging with the strongest and most effective partners in the war against fraud."

- Shumate



FOCUS Initiative for Data Miners Filing Qui Tam Complaints

The size and complexity of federal benefits programs and the lack of consistent controls to prevent their exploitation have resulted in widespread waste, fraud, and abuse at the expense of the American taxpayer. On April 7, the Department of Justice launched the first-ever National Fraud Enforcement Division (NFED) to investigate and prosecute those who steal or fraudulently misuse taxpayer dollars. The Department is committed to coordinating with agencies who administer benefits programs to combat fraud to the fullest extent possible. At the same time, the 342 million American citizens play an important role in amplifying the Department's resources and helping to identify potential fraud that might otherwise go undetected. The Department welcomes the help of American taxpayers to pursue fraud involving taxpayer dollars through False Claims Act (FCA) qui tam complaints, and through this work the Civil Division will support the NFED's anti-fraud work.

The Department received a record number of FCA qui tam complaints (980) in Fiscal Year 2024—a figure then dwarfed by the nearly 1,300 qui tam complaints received in Fiscal Year 2025. So far in Fiscal Year 2026, the Department has already received over 780 qui tam complaints, putting the Department on pace for another record. Much of this recent increase has been driven by companies or individuals who analyze publicly available government data for potential signals of fraud (data miners), rather than relying on inside information known personally by the person filing the qui tam. Since Fiscal Year 2024, data miners have filed more than 45% of all qui tam complaints. The Department's experience with data miners, as well as the Department's own data analytics, have informed its views on best practices for partnering with data miners. The Department is announcing the Fraud Oversight through Careful Use of Statistics (FOCUS) initiative, to improve the Department's ability to prioritize working with the most successful data miners.

The quality of data-driven FCA inquiries is heavily dependent on the quality of the underlying data and the analytics applied to it. Building an FCA case through data is most effective when analysts can isolate signals within datasets that correlate strongly to fraudulent conduct. When the Department employs data analytics, it is committed to thoughtfully analyzing relevant data—much of it non-public—to identify such signals. The best data miners do the same thing with public or otherwise available data and information. Many will also take advantage of the most frontier artificial intelligence (AI) models and capabilities to further isolate and discover signals of fraud from large public datasets.

For example, data miners have been particularly active with respect to pandemic assistance loans. The Small Business Administration (SBA) has publicly released certain

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Enforcement Updates

Accelerating Review and Enhancing Enforcement in Benefits Fraud Matters



U.S. Department of Justice
Civil Division

Office of the Assistant Attorney General

Washington, DC 20044

May 27, 2026 | Shumate Memo

- Assistant Attorney General Brett A. Shumate of DOJ's **Civil Division** issued a memo directing DOJ attorneys and AUSAs handling FCA cases to dramatically compress the timeline for investigating and making intervention decisions in *qui tam* actions alleging fraud against **federally funded, state-administered benefits programs**.
  - **Review deadline:** DOJ should complete review of new benefits-fraud *qui tam* complaints within the 60-day seal period where practicable (no later than 120 days), then let the relator proceed, open a 120-day expedited investigation, or seek dismissal. Further time requires DAAG, then AAG, approval.
  - New matters promptly referred to the new National Fraud Enforcement Division for evaluation of potential criminal violations.

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June 2026 National Health Care Fraud Takedown

The DOJ's Annual National Health Care Fraud Takedown took place in June 2026:

- Targeted schemes involving over **$6.5B in false claims**
- **455** defendants charged
  - Including **90 physicians and other licensed medical professionals**
- Coordinated efforts in 56 federal districts across 45 U.S. states and territories.
  - **50 of 54** state Medicaid Fraud Control Units participating
- Largest number of **Medicaid** fraud defendants and Medicaid fraud loss charged in department history.
  - **295** defendants and over **$518M in false claims submitted to Medicaid**.

"This year's National Health Care Fraud Takedown represents the greatest whole-of-government effort to combat health care fraud in our Nation's history." - Blanche
"We are aggressively scaling our offensive against anyone using health care as a front to steal from the American people" - McDonald

Highlighted Areas
Fraudulent Wound Care Schemes
Data Fusion Center, Financial Intelligence Review Team, and Data Analytics Enhancements
Patient Harm
Medicaid Fraud
Most Wanted Fraudsters List
Illegal Opioid Distribution

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Enforcement Updates

DOJ National Fraud Enforcement Division (NFED) Priorities

August 13, 2026 | McDonald Memo 1

- Assistant Attorney General Colin M. McDonald of DOJ's new NFED issued a memo articulating five enforcement priorities:
  - Public Trust and Financial Integrity
  - **Health Care**
    - *"National health care expenditures are expected to grow from over $3 trillion a year to over $7 trillion, and estimates are that between 3–10% of that amount is lost to fraud."*
  - Internal Revenue
  - Global Trade and Commerce
  - Corporate Misconduct

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Corporate Enforcement in the Fight Against Fraud

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October 1, 2026 | McDonald Memo 2

- McDonald issued a second memo specific to the corporate enforcement program
  - Fraud prosecutors shall report any ongoing corporate investigations to the Chief of the Corporate Enforcement Section, and the Corporate Enforcement Section shall be promptly notified of any new corporate investigations or major developments in existing cases.
  - The Corporate Enforcement Section will have primary responsibility for evaluating a company's compliance with the terms of any corporate criminal resolution.
  - In opening and conducting a corporate investigation, Fraud Division prosecutors should **prioritize**:
    1. **Fraud schemes involving the health care industry, including health care fraud, distribution of controlled substances, and violations of the Federal Food, Drug, and Cosmetics Act;...**

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Enforcement Updates

Current State of the DOJ

"Including lawyers and other workers, the Justice Department has lost a net 8,900 employees since Trump took office"

(Reuters, Jan. 2026)

From Jan. 2025 to Aug. 2026, internal DOJ documents show a significant workload increase per DOJ attorney, including the group investigating significant FCA cases—Civil Commercial Litigation—with an 84% increase in workload per attorney due to the mass exodus.

(The Hill, Sep. 2026)

Sources estimate that "roughly one in five lawyers who worked in the government at the end of 2024 had left by March 2026."

(NY Times, May 2026)



Attorney General of the United States, Todd Blanche & Former Attorney General, Pamela Bondi

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Enforcement Updates

More DOJ and HHS Collaboration

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October 22, 2026

- DOJ and HHS announce a six-month pilot program for FCA self-disclosures (FCA SDPP)
- Must submit by April 22, 2027
- Benefits: No CIA, damages multiplier of 1.25-1.6, amount of remuneration paid may be used as base damages for AKS
- Does not apply to criminal conduct

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Live Course Code #1: **Trends-Live**

Attending on **October 27**:
Use Live Course Code

ON-DEMAND COURSE CODE

On-Demand Course Code #1:
OD-Trends

Attending on **On-Demand** *(after 10/27/26)*:
Use On-Demand Course Code

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OIG FAQ Updates

OIG FAQ Updates

Revised FAQ

Revised – FAQ 4

- Stark Law Compliance ≠ AKS Protection
- Separate legal frameworks
- Intent remains critical
- Referral-inducing purpose creates risk
- Independent AKS analysis required

BOTTOM LINE: An arrangement satisfying a Stark Law exception may still violate the AKS if one purpose is to induce, reward, solicit, or receive referrals.

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OIG FAQ Updates

New FAQ

Added – New FAQ 17

- FMV alone does not prevent AKS liability
- Intent and facts & circumstances remain key
- No standalone FMV protection
- FMV just one of several criteria for Safe Harbor protection

BOTTOM LINE: FMV compensation remains an important compliance component but does not by itself provide a defense to potential AKS liability.

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OIG FAQ Updates

Practical Takeaways

- Analyze arrangements separately under Stark and AKS to ensure full compliance with both
- Do not rely on FMV support alone to mitigate AKS risk. Intent, business rationale, and the surrounding facts and circumstances remain critical
- Confirm that each element of any applicable AKS safe harbor is satisfied before relying on Safe Harbor protection
- Maintain documentation supporting the arrangement's legitimate purpose, the compensation methodology, fair market value determination, and compliance analysis

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EKRA Developments

Eliminating Kickbacks in Recovery Act ("EKRA")

General

- Enacted in 2018 in response to the U.S. opioid epidemic
- Established criminal sanctions (up to $200,000 fine and 10 years imprisonment) for kickbacks related to the solicitation or receipt of remuneration for any referrals to recovery homes, clinical treatment facilities, or laboratories.
  - Criminalizes the payment, or offer of payment, to induce referrals of individuals to use the services of such providers
  - Applies to all payors, including commercial plans
  - Limited exceptions for certain discounts, non-volume-based employee/contractor compensation, waivers of certain copayments, transfers to FQHCs, etc.

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Eliminating Kickbacks in Recovery Act ("EKRA")

Recent Headlines

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Recent enforcement actions show EKRA moving from an emerging statute to a recurring enforcement tool.

APR. 29, 2024

Orange County Sober Living Homes Owner Indicted for Allegedly Paying Nearly $175,000 in Kickbacks to "Body Brokers"

MAY 23, 2024

Patient Coordinator for O.C. Sober Living Home Arrested for Alleged Kickback Payments to 'Body Brokers' and Referred Patients

March 21, 2025

Hollywood Hills Man Sentenced to Nearly 3½ Years in Federal Prison for Paying Nearly $2.9 Million in Kickbacks for Drug Addiction Patient Referrals

June 30, 2025

National Health Care Fraud Takedown Results in 324 Defendants Charged in Connection with Over $14.6 Billion in Alleged Fraud (includes 2 EKRA prosecutions in record-setting enforcement action)

March 5, 2026

Over $12 Million Medicaid Fraud Scheme Leads to More Than 14 Years in Prison

October 22, 2026

Los Angeles Health Care Fraud Takedown Results in Charges Against 15 Defendants, Including 6 Medical Professionals, Nearly $2 Billion in Loss

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Eliminating Kickbacks in Recovery Act ("EKRA")

Enforcement Actions

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COMMON ALLEGATIONS

- Per-patient payments or compensation based on referral volume/value
- Monthly referral quotas and minimum patient requirements
- Payments structured through marketing or consulting agreements
- Direct payments or other incentives offered to patients
- Commercial-insurance coverage affecting patient or referral value

TREND: Increased focus on laboratories and substance abuse treatment facilities, particularly referral-based marketing arrangements involving commercially insured patients.

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Eliminating Kickbacks in Recovery Act ("EKRA")

Landmark Decision - *U.S. v. Schena*

- *U.S. v. Schena*: Landmark Ninth Circuit Ruling Affirms Broad EKRA Application (July 11, 2025)
- First Federal Appellate Interpretation of EKRA
- Indirect Referrals Can Trigger EKRA Liability
  - Extends to payments made to third-party marketers indirectly influencing referrals
  - Scope expanded beyond payments made directly to referring physicians
- Direct patient interaction not required
- Percentage-based compensation + misleading conduct = unlawful arrangement
- March 2026: Petition for certiorari denied.

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Eliminating Kickbacks in Recovery Act ("EKRA")

Evidentiary Guidance – *U.S. v. Simons*

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May 1, 2026 Order on Motions in Limine | No. 3:25-cr-02444-JAH (S.D. Cal.)

CHARGED TERMINOLOGY

"Body broker" and "kickback" permitted where tied to the alleged conduct, statutory language, or the defendant's own communications.

KNOWLEDGE & INTENT

Articles and materials accessed through the defendant's iPhone and iCloud were admissible as contextual evidence of knowledge and intent.

FACT VS. EXPERT

Expert testimony on industry practices and concealment permitted; lay legal interpretations of EKRA excluded.

BROAD RELEVANCE

Referral texts remained relevant even if a patient was not admitted; unrelated lawful services and claims did not disprove the charged conduct.

BOTTOM LINE: Communications, terminology, and industry-practice evidence may play a significant role in proving EKRA intent and conduct, while evidence of otherwise legitimate operations may offer limited defensive value.

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Eliminating Kickbacks in Recovery Act ("EKRA")

Enforcement Actions

Enforcement Observations

- Percentage-based compensation, standing alone, is not a per se EKRA violation
- Quotas and compensation mechanics may be relevant, but "inducement" requires more
- Greater risk where marketers exert undue influence or effectively control referral decisions
- False statements, patient payments, concealment, and sham contracts may supply the additional evidence

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Eliminating Kickbacks in Recovery Act ("EKRA")

Other Significant Developments

SEPT. 25, 2026 | DOJ DENIES ACLA PETITION FOR A BROADER EKRA EMPLOYMENT SAFE HARBOR

ACLA REQUESTED

- Permit variable or commission-based compensation for employed laboratory sales representatives
- Protect arrangements so long as employees do not knowingly provide materially false or misleading information

DOJ REJECTED

- Proposal would improperly narrow EKRA to fraud-based misconduct already addressed by other laws
- False or misleading statements may show improper inducement, but are not required for an EKRA violation
- Existing framework permits compensation unrelated to referral volume

COMPLIANCE IMPACT

- No broad employee safe harbor comparable to the AKS employee safe harbor
- Review commissions, bonuses, and incentives tied to test orders, referrals, or generated business
- Document legitimate, non-referral-based compensation metrics

BOTTOM LINE: AKS-compliant employee compensation is not necessarily EKRA-compliant, particularly when compensation varies with referrals, test volume, or revenue.

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Eliminating Kickbacks in Recovery Act ("EKRA")

Practical Takeaways

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- Evaluate compensation **separately under EKRA**; AKS compliance does not necessarily mean EKRA compliance.
- Scrutinize commissions, bonuses, quotas, and other incentives tied to **referrals, test volume, or business generated**.
- Remember that EKRA can reach **indirect referrals and marketing intermediaries**.
- Percentage-based compensation is **not unlawful per se**, but surrounding evidence of improper inducement remains critical.
- Ensure agreements and documentation accurately reflect **legitimate services and non-referral-based compensation methodologies**.
- Monitor developing enforcement activity, including **DOJ enforcement actions and case law**

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Insight from Court Cases

Court Cases | Qui Tam Constitutional Challenges

Why It Mattered

- More than 76% of all FCA actions since 1986 have been filed by private relators, generating over $60B in relator awards.
- A successful constitutional challenge could unwind the government's primary fraud-recovery tool overnight.
- Two Supreme Court concurrences/dissents in the preceding two years had already invited exactly this challenge.

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Court Cases | The Supreme Court Left a Trail

Twice in three years, sitting Justices went out of their way to flag Article II concerns — even in cases that didn't require it.

Wisconsin Bell, Inc. v. United States ex rel. Heath (Feb. 21, 2025)

Kavanaugh, J., concurring

- In an otherwise unanimous, narrow statutory ruling, Justice Kavanaugh wrote separately (joined by Justice Thomas) to reiterate that qui tam "raise[s] substantial constitutional questions under Article II" and that "in an appropriate case, the Court should consider" them.

U.S. ex rel. Polansky v. Executive Health Resources (2023)

Thomas, J., dissenting

- Justice Thomas's dissent (joined in relevant part by Justices Kavanaugh and Barrett) argued qui tam "wield[s] executive authority" without proper appointment, and that "there are substantial arguments" the device violates Article II.
- **Bottom line:** At least two, and possibly three, sitting Justices have signaled they are ready to grant cert "in an appropriate case." *Zafirov* was widely seen as that case.

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Court Cases | Qui Tam Constitutional Challenges

Zafirov: The Case That Shook Qui Tam

- **Allegation:** *U.S. ex rel. Zafirov v. Florida Medical Associates, LLC*. A physician-relator alleged her employer upcoded Medicare diagnoses to inflate reimbursement.
- **DOJ's role:** DOJ declined intervention on the merits, but intervened solely to defend the qui tam mechanism's constitutionality after defendants challenged it.
- **Challenge:** Defendants argued that relators are unappointed "officers of the United States" exercising core executive power, violating the Appointments Clause. They also raised Take Care and Vesting Clause theories.
- **Ruling:** On Sept. 30, 2024, Judge Kathryn Kimball Mizelle (M.D. Fla.) dismissed the case, becoming the first federal judge to hold the FCA's qui tam provisions unconstitutional.

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Court Cases | Every Circuit to Rule Rejected the Challenge — But Doubts Grew

Circuit	Case	Holding / Significance
5th Cir.	*Riley v. St. Luke's Episcopal Hosp. (en banc, 2001)*	Binding precedent: relators aren't "officers" because they lack a continuing, formalized employment relationship with the government.
5th Cir.	*Montcrief v. Peripheral Vascular Assocs. (Mar. 2025)*	Bound by *Riley*, but Judge Duncan's concurrence argued the qui tam device violates the Appointments and Take Care Clauses.
5th Cir.	*Gentry v. Encompass Health Rehab. (Nov. 3, 2025)*	Judge Ho wrote separately urging the full Fifth Circuit to "revisit" *Riley* "in an appropriate case," citing Justice Thomas's *Polansky* dissent.
6th Cir.	*In re TriHealth, Inc. (Jan. 9, 2026)*	Denied interlocutory appeal; *Taxpayers Against Fraud v. GE* (1994) forecloses the challenge absent en banc review.
9th & 10th Cir.	Prior precedent, reaffirmed through 2026	Both circuits' existing rulings that relators are not Appointments Clause "officers" remained undisturbed.

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Court Cases | Eleventh Circuit Reverses (Sept. 1, 2026)

Relators are not "officers of the United States" — qui tam survives the Appointments Clause challenge

Applying *Lucia v. SEC*'s two-part officer test, the panel (Branch, Luck, Moreno) reached only the "continuing position" prong:

- **Intermittent, Not Continuing:** A relator's role lasts only the length of one case; tenure is not permanent or pre-determined.
- **No "Continuing Emolument":** Payment is a single, contingent award tied to success — not ongoing compensation like a salaried office.
- **Personal, Non-Transferable:** The relator's duties belong to that individual alone and cannot be assumed by anyone else.

Result: The Eleventh Circuit joins the Fifth (en banc), Sixth, Ninth, and Tenth Circuits in rejecting this challenge — avoiding a circuit split and leaving qui tam intact nationwide, for now.

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Court Cases | What the Fight Left Unresolved

The Eleventh Circuit's ruling was deliberately narrow — and a parallel challenge is already before another circuit.

- **Take Care & Vesting Clauses (on remand):** The panel assumed but never decided "significant authority" under *Lucia*'s first prong, and left the Take Care and Vesting Clause theories for the district court to address on remand.
- **Third Circuit: *Penelow v. Janssen Products*:** Oral argument held March 2026 in J&J's appeal of a $1.6B verdict; the Chamber of Commerce and other amici urged the court to strike qui tam down on all three Article II theories.
- **A Cert Petition Is Likely:** Commentators expect the losing side in *Zafirov* (or *Penelow*) to seek Supreme Court review — and at least two Justices have already signaled interest.

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FCA Litigation | Key Rulings

Materiality, Pleading & Medical Necessity

Issue	Developments
Materiality	*U.S. ex rel. Streck v. Eli Lilly* (7th Cir. Sept. 11, 2025) – affirmed $183M judgment for underreported drug prices; cert. denied May 18, 2026 *United States v. LabQ Clinical Diagnostics* (S.D.N.Y. Mar. 20, 2026) – materiality adequately alleged under all three Escobar factors *U.S. ex rel. McCullough v. Anthem* (S.D. Ind. Aug. 20, 2026) – no materiality where Indiana Medicaid kept paying with actual knowledge of the alleged violations
Rule 9(b) pleading	*Wood v. Siemens* (2d Cir. Feb. 24, 2026) – must identify specific defective shipments and customers that submitted claims *U.S. ex rel. Solano v. Barton Assocs.* (1st Cir. May 28, 2026) – "Medicare eligible" patients insufficient to show claims were presented *U.S. ex rel. Kyer v. Thomas Health Sys.* (4th Cir. June 4, 2026) – claim tables and cost-report certifications insufficient without how each claim was false
Medical necessity	*U.S. ex rel. OMNI Healthcare v. MD Spine Solutions* (1st Cir. Dec. 1, 2025) – labs may rely on physician orders absent red flags *United States v. Ferncreek Cardiology* (E.D.N.C. Dec. 12, 2025) – jury found for the defendant on FCA allegations that a cardiology group billed for medically unnecessary procedures. Treating physicians permitted to testify absent expert witness disclosure.

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FCA Litigation | AKS Willfulness

Further Insight Into What it Means

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Second Circuit (2024) | *U.S. ex rel. Hart v. McKesson Corp*

- Good faith belief in legality = not willful.
- Must prove that Defendant knew conduct was unlawful.

Fifth Circuit (2025) | *United States v. Donofrio*

- Knowledge of illegality is sufficient, need not be statute specific.

Second Circuit (2025) | *U.S. ex rel. Sisselman v. Zocdoc, Inc.*

- Relying on favorable AO can be a scienter shield

Second Circuit (2026) | *United States v. Reyes*

- Willful encompasses reckless conduct (in context of FBAR statute)

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Litigation | CMP Authority

In the Aftermath of *Jarkesy*

In ***Sligo Creek Center v. U.S. Dep't of Health & Human Servs.,*** 177 F.4th 556 (4th Cir. 2026), *petition for cert. docketed* (Oct. 8, 2026).

- Fourth Circuit upheld CMS' authority to impose CMPs against a SNF for immediate jeopardy violations.
- First circuit court to address HHS CMP processes since *Jarkesy*
- *Sligo* distinguished from *Jarkesy*, relying upon the public rights exception
  - CMS CMPs in this context, unlike claims grounded in common law, arise out of a complex regulatory scheme and apply only to SNFs who voluntarily participate in the government program.
  - *"Congress did not merely repackage (or assign to a different party) a common law cause of action when it authorized proceedings like the one HHS initiated here."*

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STARK LAW & ANTI-KICKBACK STATUTE
Shifting Focus: How Courts Are Actually Ruling

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STARK LAW

Strict liability — no intent required. A prohibited financial relationship plus a referral for designated health services violates the law.

Compensation must reflect fair market value, be commercially reasonable, and not vary with referral volume/value.

ANTI-KICKBACK STATUTE

Intent-based: prohibits knowingly offering, paying, soliciting, or receiving remuneration to induce referrals.

Under the "one purpose" test — now adopted in at least eight circuits — liability attaches if even one purpose of the payment was to induce referrals, regardless of other legitimate reasons.

The three cases that follow show courts drawing the line between ordinary business practice and unlawful referral-driven compensation.

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STARK LAW & ANTI-KICKBACK STATUTE — CASE LAW
Court Cases | 4th Cir.: wRVU Pay Isn't Automatically a Kickback

United States ex rel. Kyer v. Thomas Health System, Inc. (4th Cir. June 4, 2026)

- A former nurse's 83-page qui tam complaint alleged Thomas Health's wRVU-based physician compensation and intercompany subsidies violated Stark and AKS over a nine-year period.

- The Fourth Circuit affirmed dismissal under Rule 9(b), holding productivity-based (wRVU) compensation reflects a physician's own personally performed work — not the volume or value of referrals — even where services generate hospital facility fees.

Key line: an FCA complaint must "identify the fire," not just accumulate "smoke" from high compensation percentiles and conclusory labels.

DEFENSE WIN: Standard productivity compensation, benchmarked to fair market value, is not per se evidence of a Stark or AKS violation — even paired with high-volume referrals.

Rule 9(b) remains a meaningful gatekeeper: relators must plead specifics tying compensation to referral volume, not just characterize ordinary industry practice as fraud.

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STARK LAW & ANTI-KICKBACK STATUTE — CASE LAW
Court Cases | 2nd Cir.: The "One Purpose" Test Lowers the Bar

United States ex rel. Camburn v. Novartis Pharmaceuticals Corp. (2nd Cir. Dec. 27, 2024)

- Relator alleged Novartis ran sham "peer-to-peer" speaker programs — with no legitimate attendees and inflated fees — to induce physicians to prescribe Gilenya, an MS drug requiring a burdensome monitoring protocol.
- The Second Circuit expressly adopted the "at least one purpose" rule: a payment violates the AKS if even one purpose (not the sole or primary purpose) was to induce referrals or prescriptions — even where legitimate purposes (education, patient care) also existed.
- In doing so, the Second Circuit joined the First, Third, Fourth, Fifth, Seventh, Ninth, and Tenth Circuits already applying this standard.
- The ruling revived the relator's claims for further proceedings on the adequacy of the pleadings.

ENFORCEMENT WIN: Legitimate business purposes no longer insulate an arrangement if inducing referrals was even a secondary motive.

With 8 of 13 circuits now on board, the "one purpose" test is close to a national standard. Speaker programs, consulting fees, and similar physician-facing spend need documented, dominant legitimate purposes.

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Court Cases | E.D. Tenn.: Downstream-Revenue Comp Survives Dismissal

United States v. Erlanger Health System; U.S. ex rel. Tabor & Sullivan v. Erlanger (E.D. Tenn., Feb.–Mar. 2026)

- Two related suits — a 2021 qui tam by Erlanger's former CFO and Chief Compliance Officer, and DOJ's own 2024 intervention complaint — allege a post-2013 strategy of hiring physicians to capture referral-driven "downstream revenue."
- Allegations include compensation exceeding FMV for employed physicians, unlawful incentives to non-employed referring physicians, and dismantling of compliance controls installed after a 2010 settlement of similar claims.
- Judge Curtis Collier denied Erlanger's motion to dismiss the DOJ complaint (Feb. 26, 2026) and the whistleblowers' complaint (Mar. 9, 2026) — rejecting the argument that reliance on outside FMV consultants defeats the claims at the pleading stage.
- Potential exposure, per DOJ, exceeds $100M; Erlanger previously paid $40M in 2010 to resolve similar Stark allegations.

ENFORCEMENT WIN (SO FAR): A favorable FMV opinion doesn't insulate a hospital when the pleaded facts show compensation was structured around anticipated referral revenue.

This is a motion-to-dismiss ruling, not a merits finding — but it puts both cases into discovery, where internal comp analyses and board materials become fair game.

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Key Takeaways

Insights from Court Cases

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Qui tam survives — for now.

Every circuit to decide the Appointments Clause challenge (5th *en banc*, 6th, 9th, 10th, 11th) has rejected it, but Take Care/Vesting Clause theories remain live on remand, and *Penelow* is pending in the Third Circuit.

Preserve the constitutional argument in pending matters; monitor for a cert petition following *Zafirov* or *Penelow*.

Productivity-based (wRVU) compensation benchmarked to FMV remains defensible (*Kyer*) — but the "one purpose" test (*Camburn*) means any referral-inducing motive, however secondary, can create AKS exposure.

FMV consultant opinions are evidence, not immunity (*Erlanger*) — substance, documentation and ongoing monitoring matter more than paperwork.

Rule 9(b) remains a real gatekeeper: relators must plead specific facts connecting compensation to referral volume, not just recite high pay percentiles.

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OD-Regulatory

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Use On-Demand Course Code

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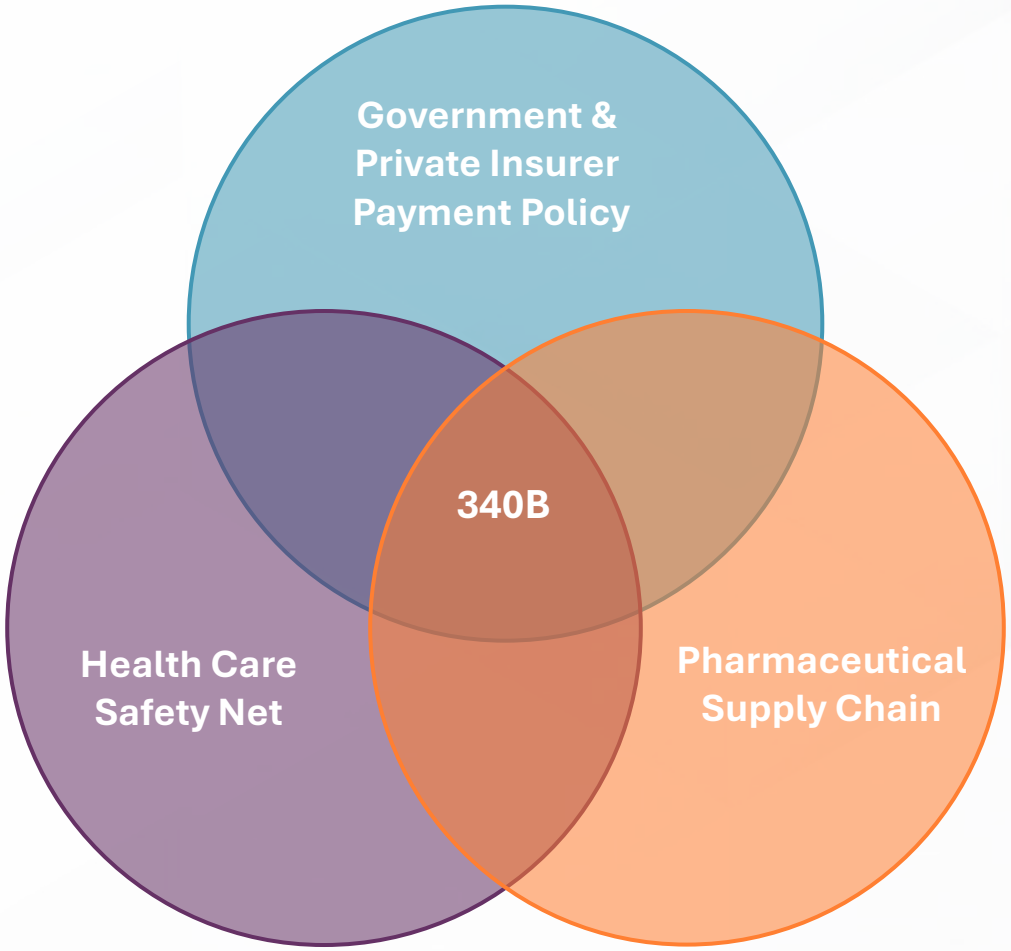


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Compliance in the 340B Program

340B Program Overview

Conceptualizing 340B



Medicare Payment Policy

- Outpatient drug reimbursement
- DSH percentage sets eligibility
- Site-of-service rules

Health Care Safety Net

- DSH and critical access hospitals
- FQHCs, Ryan White, hemophilia
- Uncompensated care obligations

Pharmaceutical Supply Chain

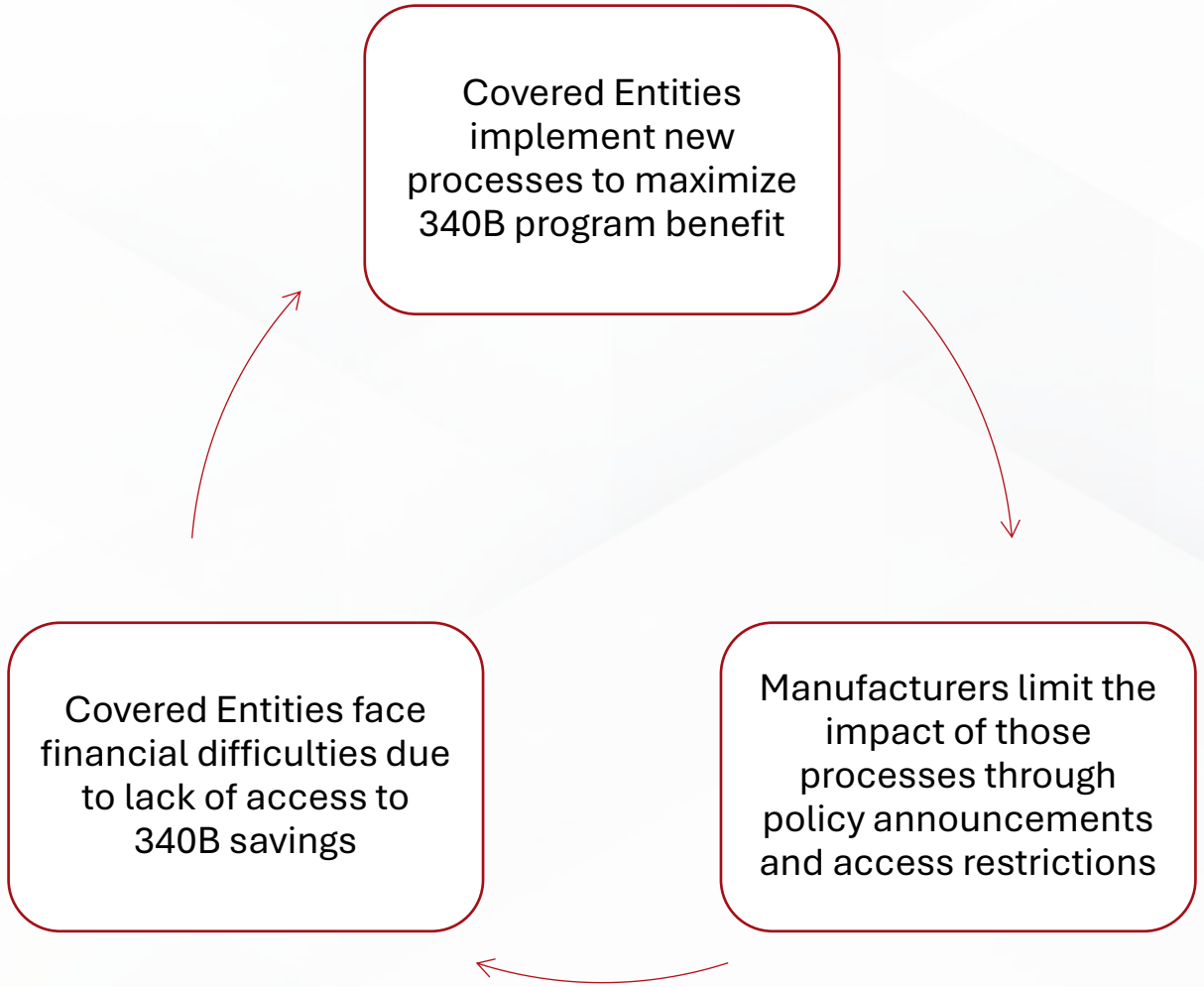
- Ceiling prices and rebates
- Wholesalers, pharmacies, PBMs
- Duplicate discount and diversion

340B lacks a robust regulatory home of its own — it borrows authority from each system, which is why oversight gaps and manufacturer restrictions keep surfacing.

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Why Care Now?

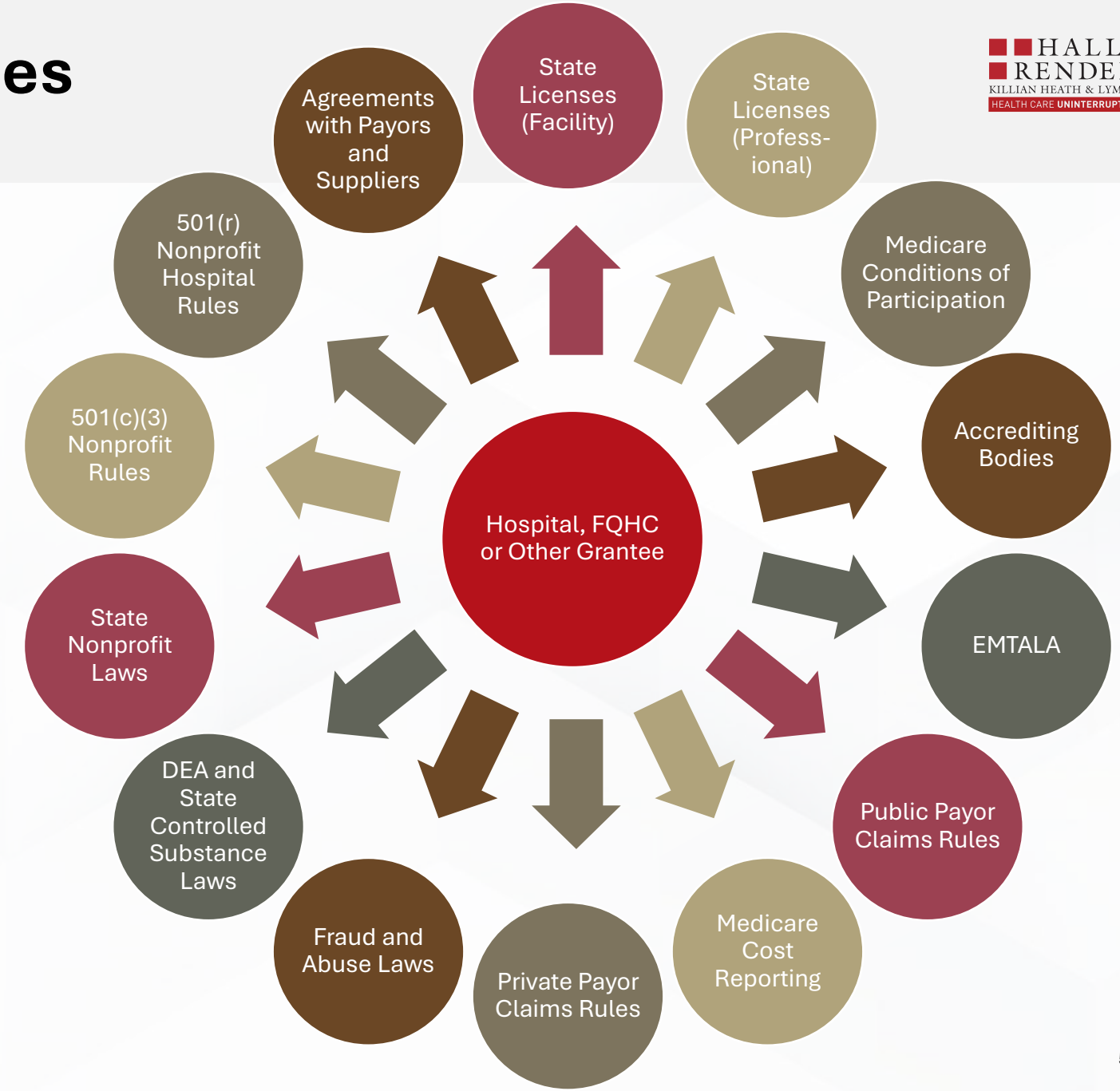
The Cycle Since 2020



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56

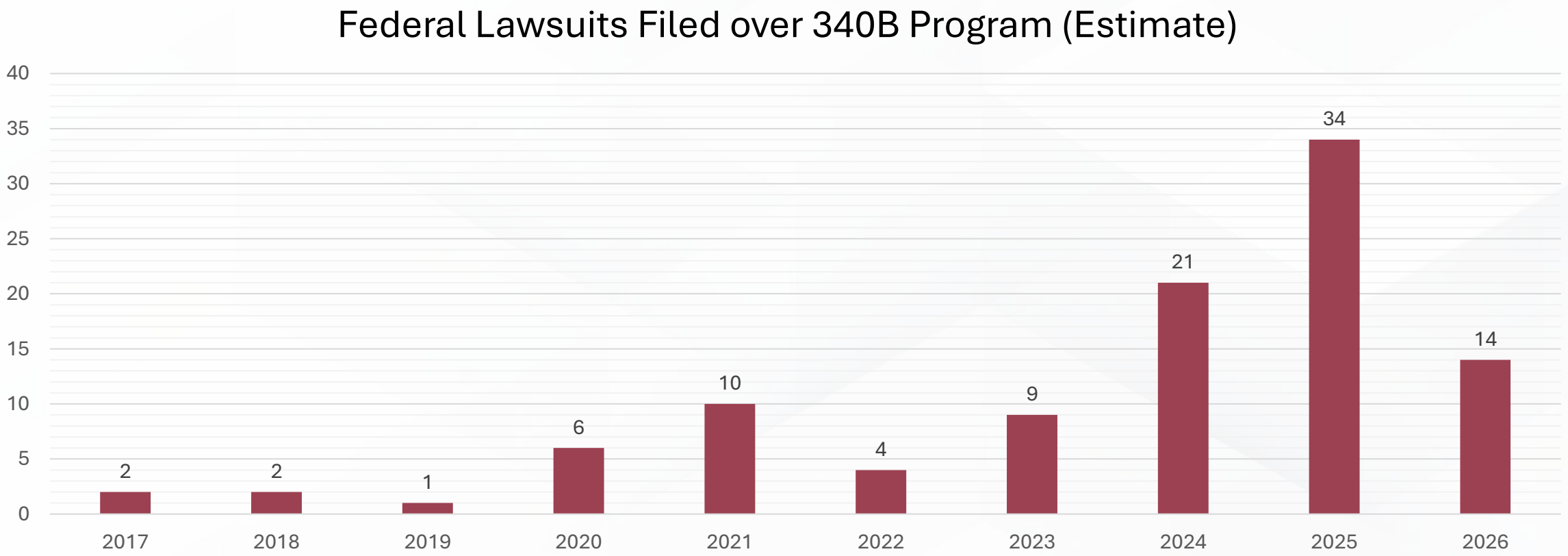
340B Program Authorities

None of these are specific to 340B



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Recent History



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What Do Those Suits Tell Us?

Principle	Citations
Covered Entities are not third-party beneficiaries to the agreement between manufacturers and HHS, so they cannot sue manufacturers for program violations under that theory.	*Astra v. Santa Clara Cty.*, 563 U.S. 110 (2011)
The 340B statute does not, on its face, require unconditional access to 340B pricing. Two Circuit Courts of Appeal have rejected HRSA's position that manufacturers cannot impose any conditions on contract pharmacy shipments; one decision is still pending (7th Circuit). These cases did not meaningfully analyze particular conditions, so there is little guidance as to what is allowed and what is not.	*Sanofi Aventis U.S. v. HHS*, 58 F.4th 696 (3d Cir. 2023); *Novartis v. Johnson*, 102 F.4th 452 (D.C. Cir. 2024); *Eli Lilly v. Kennedy* (7th Cir. Case No. 21-3128)
States can require manufacturers to ship their products to contract pharmacies. The 340B statute is silent as to delivery, so states can step in without violating the Supremacy Clause.	See, e.g., *AbbVie v. Murrill*, 180 F.4th 747 (5th Cir. 2026).
Manufacturers cannot switch from a discount to a rebate without HHS's prior approval.	*Novartis v. Kennedy*, 182 F.4th 1027 (D.C. Cir. 2026)
HRSA cannot require covered entities to demonstrate patient eligibility on a prescription-by-prescription basis.	*Genesis Health Care, Inc. v. Becerra*, 701 F. Supp. 3d 312 (D.S.C. 2023).
Grantees under certain programs (including STD grants) are not eligible unless their grant comes directly from the state or federal government.	*Amgen v. Becerra*, 2026 WL 2364336 (D.D.C. 2026)

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340B DRUG PRICING PROGRAM — CASE LAW
Court Cases | 9th Cir.: Astra Is Not a Blanket Bar on Covered Entity Suits

United States ex rel. Adventist Health System of West v. AbbVie Inc. (9th Cir. Mar. 17, 2026)

- Adventist, a 340B covered entity, brought a qui tam FCA action alleging manufacturers inflated ceiling prices on 340B drugs, causing federal and state governments to overpay through Medicaid and Medicare reimbursement.
- The district court dismissed with prejudice, reading *Astra USA v. Santa Clara County* to bar any claim arising from alleged 340B violations because the statute has no private right of action and Congress created the HRSA ADR process.
- The Ninth Circuit reversed: Adventist sues on behalf of the government under the FCA, not for its own overcharges, so it is not "in essence" enforcing Section 340B. *Astra* involved a common-law breach-of-contract suit for compensatory damages — categorically distinct.

KEY TAKEAWAY: Federal circuits are not reading *Astra* as a complete bar on suits between covered entities and manufacturers.

Astra bars repackaged 340B claims seeking the entity's own recovery — not FCA claims pled for the government's losses.

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Compliance Landmarks

Activity	Key risk areas
Using 340B drugs in the four walls of a hospital or within the scope of a qualifying federal grant	340B prohibition on diversion 340B prohibition on duplicate discounts Claim billing & modifier requirements for Medicare, Medicaid, and private payors Manufacturers' patient assistance programs Manufacturers' medical claims submission policies (HIPAA, state privacy law, data vendor contract, post-purchase manufacturer inquiries)
Using 340B drugs in a different location	Medicare provider-based rules (hospital) HRSA child site registration requirements (hospital) Grant requirements (grantee) HRSA associated site registration requirements (grantee)
Dispensing 340B drugs through an entity-owned pharmacy	State & federal rules on operating a pharmacy Manufacturers' pharmacy claims submission policies PBM billing requirements Third-party administrator agreement
Dispensing 340B drugs through a contract pharmacy	Contract Pharmacy Services Agreement Distributor relationships HRSA contract pharmacy registration requirements

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Focus on DEI

Civil Rights Laws + False Claims Act

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DOJ Civil Rights Fraud Initiative memorandum

Issued by Todd Blanche, then Deputy Attorney General and now Attorney General.

The memorandum links compliance with federal civil rights laws to False Claims Act exposure for recipients of federal funds.

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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

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First DEI FCA Settlement

On April 10, 2026, IBM agreed to pay $17 million to resolve DEI-based FCA claims.

Associate Attorney General and Deputy Assistant Attorney General signed the settlement agreement.

- No line-level prosecutors

Covered conduct went back to 2019.

IBM allegedly used race, color, and sex to: (1) adjust compensation; (2) make hiring and promotion decisions; (3) develop goals for business units; and (4) offer training to certain employees.

Settlement does not mention which IBM federal contracts contained civil rights provisions that IBM allegedly violated.

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Second DEI FCA Settlement

On August 21, 2026, Deloitte agreed to pay $21.5 million to resolve DEI-based FCA claims and $1.2 million to the State of Indiana.

Associate Attorney General, Assistant Attorney General, and Deputy Assistant Attorney General signed the settlement agreement.

- Along with two DOJ Trial Attorneys and one AUSA

Based on a qui tam lawsuit filed on April 25, 2025.

- Relator received $4.3 million from DOJ and $240,000 from Indiana

Covered conduct went back to January 2017.

Deloitte allegedly used race, color, and sex to: (1) make hiring and promotion decisions, including tracking demographic goals; (2) evaluate employees and adjust compensation based on diversity goals; and (3) offer training, mentoring, and leadership opportunities to certain employees.

Deloitte certified its compliance with civil rights laws in federal contracts and in Indiana contracts.

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Third DEI FCA Settlement

On September 14, 2026, Accenture agreed to pay $25 million to resolve DEI-based FCA claims.

Associate Attorney General, Assistant Attorney General, Deputy Assistant Attorney General, and Chief of the Commercial Litigation Branch signed the settlement agreement.

- No line-level prosecutors
- No underlying qui tam lawsuit

Covered conduct went back to January 2017.

Accenture allegedly used race and sex to: (1) make hiring and promotion decisions, including tracking demographic goals; and (2) offer training, mentoring, and leadership opportunities to certain employees.

Accenture certified its compliance with civil rights laws in federal contracts.

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DOJ Best Practices

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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

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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

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Practical Takeaways

1. Prepare for surging FCA enforcement
2. Review DEI policies and initiatives
3. Monitor AI and data use
4. Strengthen compliance systems

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Questions

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Appendix

Notable Settlements and Recent Fraud and Abuse Developments

Appendix | Notable Settlements (Part 1)

MA Risk Adjustment, Wound Care & Pharma

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Medicare Advantage Risk Adjustment

- **Kaiser Permanente | $566M (Jan. 2026)** – unsupported diagnosis codes; largest MA risk-adjustment FCA settlement
- **The Villages Health | $541.5M (Aug. 2026)** – self-disclosed unsupported diagnosis codes
- **Aetna | $117.7M (Mar. 2026)** – submitted or failed to withdraw unsupported codes; refused CIA, OIG reserved exclusion authority
- **Matrix Medical Network (HealthFair) | $56.5M (June 2026)** – diagnoses lacking documentation or based only on patient attestation
- **Complete Health | $14.1M (Aug. 2026)** – MSO paid a share of MA revenue caused submission of false codes

Wound Care / Skin Substitutes

- **Gehrke & King (Apex/Viking) | $309.9M (Dec. 2025)** – medically unnecessary amniotic grafts; tied to $1.2B criminal scheme
- **Vohra Wound Physicians | $45M (Nov. 2025)** – medically unnecessary wound care procedures

Pharmaceutical Manufacturers

- **Veloxis Pharmaceuticals | $46M (Aug. 2026)** – specialty-pharmacy kickbacks; largest Sunshine Act recovery
- **Dompé U.S. | $32M (Sept. 2026)** – Medicare copays paid through patient assistance foundations
- **Takeda Pharmaceuticals | $13.6M (May 2026)** – kickbacks to physicians to prescribe an antidepressant

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Appendix | Notable Settlements (Part 2)

Labs, Physician Arrangements & Medicaid

Laboratory Testing

- **Advanced Pathology Solutions | $30M + CIA (June 2026)** – "lean lab" kickbacks to GI practices; unnecessary testing
- **Magnolia Diagnostics | $19.2M (July 2026)** – unnecessary respiratory panels bundled with COVID-19 testing
- **LabCorp | $14.5M (July 2026)** – unnecessary definitive urine drug testing
- **NeoGenomics Laboratories | $9.8M (July 2026)** – self-disclosed below-FMV consulting services to referral sources

Stark/AKS Physician Arrangements *(Traditions Health and Modern Nuclear: see Sham Arrangements slide)*

- **NewYork-Presbyterian Hudson Valley | $6.8M (Dec. 2025)** – kickbacks to an oncology practice for referrals
- **OASIS / USPI / Dignity | $5.6M (Feb. 2026)** – self-disclosed interest payments on bonds issued to physician group
- **Trinity Hospital Holding Co. | $1.7M (Apr. 2026)** – self-disclosed noncompliant physician rental arrangements
- **Medical Services of America / Traditional Home Care | $702K (Jan. 2026)** – bonuses tied to physician-spouse referrals

Medicaid & Services Not Rendered

- **Choice HomeCare | $34.9M** – self-disclosed billing for in-home care hours not provided
- **Oglethorpe Inc. | $32M + 10-yr exclusion (May 2026)** – retained overpayments; breached existing CIA
- **Journey to Hope | $10.2M (June 2026)** – substance use disorder services not provided

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Appendix | Enforcement Trends | MA

Medicare Advantage: Why MA Is a Top Enforcement Priority

Follow the Money

- **2026:** 55% of eligible Medicare beneficiaries (35.2M) enrolled in MA; payments to MA plans estimated at $574B
- **Government spends an estimated 14% more** on MA enrollees than on traditional Medicare beneficiaries (~$76B)
- **February 2026:** OIG issued Medicare Advantage Industry-Specific Compliance Program Guidance

Marketing & Broker Kickbacks

- **U.S. ex rel. Shea v. eHealth, Inc.,** No. 21-cv-11777 (D. Mass. Mar. 25, 2026)
  - Court denied motions to dismiss DOJ-intervened claims that Aetna, Elevance, and Humana paid brokers (eHealth, GoHealth, SelectQuote) kickbacks disguised as "marketing" payments to steer enrollment
  - AKS violation adequately alleged under both "but-for" causation and false certification theories; disability-discrimination allegations against Aetna and Humana proceed; unjust enrichment claim dismissed

Risk Adjustment Litigation

- **U.S. ex rel. Zafirov v. Florida Medical Associates,** No. 24-13581 (11th Cir. Sept. 1, 2026) – MA risk-adjustment qui tam revived after the Eleventh Circuit rejected the Appointments Clause challenge (see FCA Litigation Developments)

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Appendix | Enforcement Trends | MA

Medicare Advantage: Risk Adjustment Resolutions

Entity	Amount	Date	Allegations / Notes
Kaiser Permanente	$566M	Jan. 14, 2026	Unsupported diagnosis codes; largest MA risk-adjustment FCA settlement; no CIA
The Villages Health	$541.5M	Aug. 26, 2026	Self-disclosed unsupported or undocumented diagnosis codes; DOJ credited disclosure, remediation, and cooperation
Aetna	$117.7M	Mar. 11, 2026	Submitted or failed to withdraw inaccurate codes; refused CIA, and OIG reserved exclusion authority
Matrix Medical Network (HealthFair)	$56.5M	June 3, 2026	Diagnoses made without documentation or based only on patient attestation or history
Complete Health Partners	$14.1M	Aug. 3, 2026	MSO that received a percentage of MA payments caused submission of false diagnosis codes
Monogram Health	$2.4M	Aug. 24, 2026	Caused submission of false diagnosis codes; received cooperation credit

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Appendix | Enforcement Trends | Wound Care

Skin Substitutes: Spending Surge Drives Enforcement

Background

- **September 2025:** OIG report found Medicare Part B payment trends for skin substitutes raise major concerns about fraud, waste, and abuse
- **Skin substitute dollars:** $400M (2022) → $10B (2024) → $15B (2025)
- **June 2026 Takedown:** fraudulent wound care schemes were a highlighted enforcement area

Notable Actions

- **Gehrke & King (Apex Medical / Viking Medical) | $309.9M (Dec. 2025)** – medically unnecessary amniotic grafts; related criminal pleas in a $1.2B scheme; sentenced to 14 and 15.5 years
- **Vohra Wound Physicians | $45M (Nov. 2025)** – medically unnecessary wound care procedures
- **Expert Wound Care (pending)** – May 2026, court authorized seizure of more than $2M; alleged billing for skin substitutes and grafts never performed

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Appendix | Enforcement Trends | Lab Testing

Medical Necessity & Kickback Theories

Medical Necessity

- **U.S. ex rel. OMNI Healthcare, Inc. v. MD Spine Solutions LLC** (1st Cir. Dec. 1, 2025)
  - Affirmed SJ for lab: physician orders evidence medical necessity; labs may rely on them absent red flags

"Lean Lab" Arrangements: DOJ Pursued Every Party

- **Advanced Pathology Solutions | $30M + CIA (June 2026)** – set up limited-purpose labs in GI practices that let practices bill for slide preparation, alleged as kickbacks to induce referrals; also volume-based commissions and unnecessary "confirmatory" testing

OIG Guidance

- **AO 26-02** – approved an urgent care management entity's lab because no remuneration was paid for referrals, but OIG warned of abusive arrangements in which management entities affiliated with labs funnel kickbacks

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Appendix | Enforcement Trends | Lab Testing

Notable Resolutions

Entity	Amount	Date	Allegations
Magnolia Diagnostics	$19.2M	July 2026	Unnecessary respiratory pathogen panels bundled with COVID-19 testing; standing orders across senior living communities
LabCorp	$14.5M	July 2026	Billed both comprehensive and definitive urine drug testing on the same sample; unnecessary definitive testing
NeoGenomics Laboratories	$9.8M	July 2026	Self-disclosed below-FMV consulting services furnished to referral sources (AKS/Stark)
Patients Choice Laboratories	$9.62M	Nov. 2025	Unnecessary respiratory panels; sham “marketing services” agreement and commission-based sales reps
Aymancare PLLC	$7.5M	Aug. 2026	Overbilling for COVID-19 testing performed for uninsured patients
LTD Holding (fka Labtech Diagnostics) & CEO	$6.8M+	Jan. 2026	Kickbacks disguised as rent, phlebotomy, and equipment payments; lab also pleaded guilty to five AKS counts
DermTech	$5M	Aug. 2026	Claims for unreliable skin cancer tests

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EKRA: Eliminating Kickbacks in Recovery Act

In July 2025 the Ninth Circuit was the first federal circuit court of appeals to interpret EKRA in ***United States v Schena***, No.23-2989 (9th Cir. July 11, 2025).

- EKRA is an all-payor kickback prohibition intended to target addiction and recovery services
- Broader reach than the AKS with fewer exceptions and safe harbors.
- In Schena, the Ninth Circuit affirmed the trial courts holding that payments to 3rd party marketing intermediaries are proscribed by EKRA.
- The panel addressed what it means to "induce a referral".
  - *"[T]he plain meaning of to induce a referral of an individual includes situations where a marketer causes an individual to obtain a referral from a physician."*
  - *"[T]o induce a referral* ***of an individual*** *means merely that the ultimate object of the inducement must be a natural person to whom covered medical services would be provided."*
  - *"We do not think the mere fact of a percentage-based marketing arrangement, without more, would constitute a per se violation of EKRA. . ."* (though percentage-based payments to marketers who are directed to mislead those making the referrals is sufficient).

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Appendix | Enforcement Trends | AKS Inducement

Who Counts as a Target and what Qualifies as an Inducement?

Who is a Target?

***United States v. Sorensen*, 134 F. 4th 493 (7th Cir. 2025)**

- Seventh Circuit reversed DME owner's conviction, holding payments to patient recruiting firms fell outside AKS.
- Government must prove that recipient had "fluid, informal power and influence" over health care decisions.

What is Inducement – and Where do Patient Assistance Programs Land?

- Patient assistance programs can constitute inducement even absent corrupt intent (AO 26-17 (Aug. 2026))
  - OIG reaffirmed that manufacturer-funded patient assistance programs may provide premium and cost-sharing assistance to Medicare and Medicaid beneficiaries without AKS sanctions if the charity operates independently, determines eligibility based on financial need, and prevents manufacturers from steering patients to their products.
- **Dompé U.S. | $32M (Sept. 2026)** – Medicare copays paid through patient assistance foundations to induce purchases of Oxervate
- *Vertex Pharmaceuticals Inc. v. HHS*, 2026 WL 2617588 (D.C. Cir. Sept. 4, 2026)
  - Affirmed HHS's conclusion that the Program would violate the AKS.
  - "Induce," = "to influence or prevail on a person." "Remuneration," = anything of value, including payments below fair market value.
  - Reversed as to the Beneficiary Inducement Statute and struck down OIG's advisory-opinion timing regulations

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