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Publications

October 28, 2026 • Updates

DOJ and HHS Unveil New False Claims Act Self-Disclosure Initiative for Health Care Companies

Key Updates

- The DOJ and HHS have launched a six-month FCA Self-Disclosure Pilot Program, open through April 22, 2027, offering eligible health care organizations reduced damages and favorable settlement terms for voluntarily disclosing potential civil FCA violations unknown to the federal government.

Why It Matters

- Health care organizations that identify potential FCA violations, such as through audits, compliance investigations, or transactional due diligence, have a limited opportunity to resolve civil liability on more favorable terms by reducing financial exposure and avoiding certain administrative penalties.

Next Steps

- Health care organizations considering participation in the Pilot Program should assess potential FCA exposure and program eligibility, weighing the benefits of self-disclosure against the program's comprehensive disclosure requirements and other avenues for potential resolution before the April 22 deadline.

Health care organizations now have a six-month window to disclose and resolve potential False Claims Act (FCA) violations with the federal government, in exchange for reduced damages and other favorable settlement terms. This opportunity is offered through the FCA Self-Disclosure Pilot Program, which the Department of Justice (DOJ) Civil Division and Department of Health and Human Services (HHS) jointly launched to incentivize health care companies to self-disclose civil FCA violations that are unknown to the federal government. The Pilot Program runs through April 22, 2027, and eligibility is broadly open to entities that furnish, arrange for, manufacture, distribute, insure, administer, or bill for items or services reimbursed by HHS federal health care programs.

Participating companies may receive:

Related People

- Dayna C. Staron
- Tessa M. Lancaster

Related Capabilities

- Government Investigations
- Health Care

- **Reduced Damages Multiplier.** The FCA imposes treble damages, and DOJ routinely settles FCA cases for double damages, but the Pilot Program promises a 1.25 to 1.6 damages multiplier instead. The precise multiplier the government will apply depends on factors including disclosure timing, scope of conduct, leadership involvement, and remediation.
- **Decreased Damages Calculation for Anti-Kickback Statute (AKS) Violations.** Courts and the government typically calculate damages for FCA liability predicated on underlying AKS violations by quantifying reimbursement for all claims resulting from the AKS violation. Under the Pilot Program, however, the government has indicated it will forgo damages based on the amounts paid per claim and calculate damages by considering the amount of improper remuneration, the revenue derived from the disclosed conduct, and the absence of aggravating factors like patient harm.
- **Coordinated DOJ and HHS Resolution.** Disclosing entities will receive more favorable settlement terms than the federal government typically offers to settling parties. These terms include an FCA release without factual admissions — a significant protection given the increasing number of FCA settlements wherein the government required admissions. Additionally, HHS-OIG will not require a Corporate Integrity Agreement to resolve its permissive exclusion authority, and CMS will not impose civil monetary penalties or seek revocation as part of resolution.

Any submissions to the Pilot Program must occur by April 22, 2027, and include:

- A description of the potential FCA violations, applicable legal requirements, and the relevant time period;
- Supporting documentation sufficient to explain the nature and scope of the conduct;
- A description of corrective actions taken to terminate the conduct and prevent recurrence;
- Financial information sufficient to calculate the proposed repayment amount; and
- An authorized representative's certification attesting to the truthfulness and completeness of the disclosure.

Key Considerations for Health Care Organizations

The Pilot Program seeks to offer organizations that identify potential FCA violations, such as through internal audits, compliance investigations, or transactional due diligence, a more predictable civil resolution with favorable financial and administrative terms. It does not provide an avenue to resolve FCA liability for conduct already known to the federal government, potential criminal liability, or potential liability under state law.

Participation requires a comprehensive disclosure of conduct, including supporting documentation, financial analysis, and evidence of remediation. Organizations considering participation should carefully evaluate the scope of identified conduct, potential exposure — including potential criminal disclosure that cannot be resolved through this Pilot Program — and eligibility requirements before submitting a disclosure.

For assistance evaluating potential FCA exposure, determining eligibility for the Pilot Program, or preparing a timely and complete disclosure, please contact Dayna Staron or Tessa Lancaster at Polsinelli. Our team can help health care organizations assess their options and navigate this new Pilot Program among other options for self-disclosure.