DOJ and HHS Launch Healthcare False Claims Act Self-Disclosure Pilot Program

October 29, 2026

On October 22, 2026, the Civil Division of the U.S. Department of Justice ("DOJ") and the U.S. Department of Health and Human Services ("HHS") announced the launch of the Healthcare False Claims Act Self-Disclosure Pilot Program (the "Pilot Program").[1] The six-month Pilot Program is designed to offer companies "a clear and predictable pathway" to a coordinated resolution of civil liability under the False Claims Act ("FCA"), the statute providing for significant penalties against individuals and companies that knowingly submit, or cause the submission of, false or fraudulent claims for payment to the federal government.[2] According to the government, the Pilot Program is designed to support "legitimate American healthcare businesses endeavoring to quickly and cooperatively resolve prior misconduct and move forward with a clean slate"—not to help businesses that knowingly engage in fraud.[3] The Pilot Program has important implications both for healthcare companies and for investors when they conduct due diligence into such companies.

Overview. The Pilot Program is open to healthcare providers, suppliers, manufacturers, payors, and related entities that furnish, arrange for, manufacture, distribute, insure, administer, or bill for items or services covered by federal healthcare programs administered by HHS. To qualify, the self-disclosure must concern a potential FCA violation previously unknown to the federal government. A company that discloses a potential FCA violation that was already known to the government may be eligible for self-disclosure and cooperation credit under Justice Manual Section 4-4.112 (which sets

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1 Press Release, U.S. Department of Justice, Office of Public Affairs, Justice Department's Civil Division and the Department of Health & Human Services Announce Anti-Fraud Healthcare Self-Disclosure Pilot Program (Oct. 22, 2026), https://www.justice.gov/opa/pr/justice-departments-civil-division-and-department-health-human-services-announce-anti-fraud; Press Release, U.S. Department of Health and Human Services, Department of Health and Human Services and the Justice Department's Civil Division Announce Anti-Fraud Healthcare Self-Disclosure Pilot Program (Oct. 22, 2026), https://www.hhs.gov/press-room/hhs-doj-launch-healthcare-false-claims-act-self-disclosure-pilot.html.

2 U.S. Department of Justice and U.S. Department of Health and Human Services, Department of Justice and Department of Health and Human Services Healthcare Self-Disclosure Pilot Program, at 1, https://www.hhs.gov/sites/default/files/doj-hhs-fcas-self-disclosure-pilot-program.pdf.

3 *Id.*

out DOJ's policy for rewarding voluntary disclosure, cooperation, and corrective action), but not for a resolution under the Pilot Program.

The self-disclosure must describe all relevant information about the conduct that potentially violates the FCA, including the specific laws, regulations, or other requirements that the company believes were violated and the time period during which the violations occurred; produce documents sufficient to fully reflect the conduct; specify the remedial measures taken; provide financial information sufficient to calculate the base repayment amount; and include a certification by an authorized representative that, to the best of that individual's knowledge, the submission contains truthful and complete information about the disclosed potential FCA violations.

The Pilot Program is limited to the disclosure of civil violations. A company seeking to self-disclose potentially criminal violations must disclose that conduct to DOJ's National Fraud Enforcement Division pursuant to the National Fraud Enforcement Division's and the HHS Office of Inspector General's ("HHS-OIG") Policy on Coordination of Voluntary Self-Disclosure in Health Care Fraud Matters, issued on October 15, 2026.[4] A company that has already self-disclosed potentially criminal conduct to the Fraud Division does not need to report the same conduct again under the Pilot Program; if the company also wants a civil FCA release through the Pilot Program, the government will ask for additional information if needed.

Benefits of Disclosure. A qualifying company under the Pilot Program will receive a coordinated civil release from liability under the FCA and certain HHS administrative authorities, and will not be required to admit the facts underlying the disclosed conduct. HHS-OIG will not require the company to enter into a Corporate Integrity Agreement, and the Centers for Medicare & Medicaid Services ("CMS") will not impose civil monetary penalties or seek revocation of enrollment in the Medicare program as part of any resolution under the Pilot Program.

A company entering into a civil FCA release under the Pilot Program will have to pay 1.25 to 1.6 times the base repayment amount, with the multiplier dependent on factors such as: (1) timeliness of the self-disclosure; (2) duration and scope of misconduct; (3) involvement of senior leadership; (4) financial benefit to the company; and (5) if the company was a successor to the entity that engaged in the misconduct, whether the

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[4] National Fraud Enforcement Division and HHS Office of Inspector General, National Fraud Enforcement Division and HHS-OIG Policy on Coordination of Voluntary Self-Disclosure in Health Care Fraud Matters (Oct. 15, 2026), https://www.justice.gov/opa/media/1466291/dl?inline; Press Release, U.S. Department of Justice, Office of Public Affairs, National Fraud Enforcement Division and the Department of Health and Human Services Announce Self-Disclosure Protocol for Criminal Health Care Fraud (Oct. 15, 2026), https://www.justice.gov/opa/pr/national-fraud-enforcement-division-and-department-health-and-human-services-announce-self.

misconduct was promptly remediated. This range compares favorably to the multipliers commonly seen in negotiated FCA resolutions, which often approach 1.8 to two times the government's losses, while the FCA itself provides for treble damages and per-claim penalties.

The Pilot Program also provides special treatment for self-disclosure of violations of the Anti-Kickback Statute ("AKS"), which prohibits knowingly and willfully offering or paying anything of value to induce federally reimbursed referrals or business or soliciting or receiving such value in return. For AKS violations resolved under the Pilot Program, the government will forgo damages based on claims-paid amounts and instead will calculate the base repayment by reference to the amount of the payments or other benefits provided, the revenue derived from the conduct at issue, and the absence of aggravating factors such as patient harm. The Pilot Program's protocol includes an example illustrating this approach, in which a company acquires a healthcare company and discovers after closing that the acquired business may have engaged in conduct violating the AKS.

The Pilot Program is new, and it remains to be seen how DOJ, HHS-OIG, and CMS will administer it. Self-disclosure entails many risks, including the possibility that DOJ may investigate the company's executives and employees and may seek the company's cooperation in any such investigation.

Practical Implications. The Pilot Program offers a defined set of benefits that may make self-disclosure of potential FCA violations more attractive than in the past. The Pilot Program protocol's example of an acquirer that discovers potential misconduct after closing reinforces that private equity firms and other investors should consider whether disclosure may be warranted when historical misconduct is identified at an acquired business.

Companies that identify issues that may potentially give rise to FCA liability should carefully assess whether the conduct may be criminal or civil and evaluate whether and where to self-report. They should also consider the potential repercussions from self-disclosure and confirm that any submission can meet the Pilot Program's requirements before the April 22, 2027, deadline.

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Please do not hesitate to contact us with any questions.



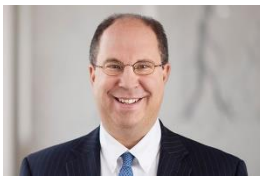
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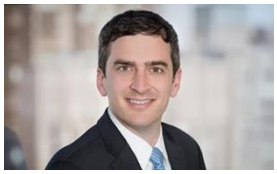
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