

HEALTH LAW WEEKLY

October 23, 2026

A New Self-Disclosure Landscape for Health Care Companies: What In-House Legal and Compliance Teams Need to Know

Kevin Lowell, Miller & Chevalier Chartered

Bradley Markano, Miller & Chevalier Chartered

Mena Sawyer, Miller & Chevalier Chartered

On October 15, 2026, the Department of Justice's (DOJ's) National Fraud Enforcement Division (Fraud Division) and the Department of Health and Human Services Office of Inspector General (HHS-OIG) issued a joint policy establishing the Fraud Division's Health Care Fraud Section as the single point of entry for companies seeking to self-disclose potentially criminal conduct related to health care and clarifying and streamlining the process for such disclosures.^[1] A company that discloses to the Section now receives the benefits of both DOJ's Corporate Enforcement and Voluntary Self-Disclosure Policy (CEP) and HHS-OIG's Health Care Fraud Self-Disclosure Protocol (SDP), with no separate HHS-OIG submission.^[2] One week later, DOJ's Civil Division and HHS added a civil counterpart: a six-month pilot program offering a coordinated, reduced-multiplier resolution for companies that self-disclose potential False Claims Act (FCA) violations.

For in-house legal and compliance teams at health care and life sciences companies, these developments reshape the factors to consider when evaluating potentially criminal conduct uncovered in an internal review, including whether, and where, to disclose the conduct to government enforcement authorities. It also arrives as corporate health care enforcement is accelerating, which makes the work those teams do before a problem surfaces more important than ever.

A Fraud Division Built for Speed and Scale

The numbers tell the story. Before 2025, DOJ's health care fraud prosecutors had not entered into a corporate criminal resolution in nearly a decade; their work centered on individual providers, marketers, and executives.^[3] That changed quickly. In August 2025, the Health Care Fraud Unit entered into a non-prosecution agreement with Troy Health, Inc. over fraudulent Medicare Advantage enrollments^[4] and, with the Consumer

Copyright 2026, American Health Law Association, Washington, DC. Reprint permission granted.

Protection Branch, a deferred prosecution agreement with Kimberly-Clark Corporation of up to \$40.4 million involving adulterated surgical gowns.^[5] In December 2025, the Unit indicted two companies on controlled substance charges.^[6] In March 2026, the New England Strike Force and the U.S. Attorney's Office for the District of Massachusetts reached a deferred prosecution agreement with ExThera Medical Corporation for failing to report adverse events, including two patient deaths.^[7] In July 2026, the Fraud Division issued its first CEP declination to a health care company.^[8] That is at least six corporate enforcement actions in roughly one year for the Division, after nearly a decade with little to no corporate enforcement activity by the DOJ's Criminal Division.

The institution behind those cases has grown just as quickly. DOJ created the Fraud Division in April 2026, consolidating fraud enforcement previously housed in the Criminal Division.^[9] The Division's August 2026 priorities memorandum calls for rapid expansion through 2028 and pairs prosecutors with data scientists and corporate enforcement specialists.^[10] The Health Care Fraud Section now operates nine strike forces, and the Division runs artificial intelligence and analytics directly on federal health care program data.^[11] On October 1, 2026, Assistant Attorney General (AAG) Colin M. McDonald's Directive 26-12 named health care fraud, including violations of the Federal Food, Drug, and Cosmetic Act (FDCA), as the Division's first corporate enforcement priority.^[12] The result is a more sophisticated practice that generates its own leads, moves faster from individual to corporate cases, and reaches Food and Drug Administration-regulated companies as readily as providers.

The Policy Backdrop

The joint policy builds on a familiar foundation. Since 1998, HHS-OIG's self-disclosure protocol has provided a path for providers to voluntarily resolve civil monetary penalty exposure rather than risk an enforcement action, and has typically rewarded such voluntary disclosures with a lower damages multiplier and in some cases the omission of a corporate integrity agreement.^[13] On the criminal side, the Principles of Federal Prosecution of Business Organizations have long credited disclosure, cooperation, and remediation as favorable factors weighing towards leniency in investigations and prosecutions.^[14] The Criminal Division sharpened those incentives in May 2025 with a clearer path to declination,^[15] and DOJ adopted a single Department-wide Corporate Enforcement and Voluntary Self Disclosure Policy (CEP) in March 2026.^[16]

The two tracks never fully connected. A single course of conduct, such as a kickback arrangement or billing for medically unnecessary services, frequently creates criminal, civil, and administrative exposure at once.^[17] In-house teams faced a practical question: disclose to HHS-OIG, to DOJ, or to both? The 2025 Troy Health non-prosecution agreement shows the stakes. Troy self-reported elements of the alleged misconduct to the Centers for Medicare & Medicaid Services before DOJ learned of the

conduct, but because it did not disclose to the DOJ, it received no voluntary self-disclosure credit.[\[18\]](#)

Where Criminal Disclosures Now Go

The October 15 policy simplifies the calculation. Corporations that make a good-faith voluntary self-disclosure of criminal conduct affecting a federal health care program to the Health Care Fraud Section now earn the benefits of both the HHS-OIG and DOJ self-disclosure programs.[\[19\]](#)

Importantly, HHS-OIG revised its SDP on October 15 to confirm that it is limited to civil and administrative matters, while potentially criminal conduct belongs with DOJ.[\[20\]](#) The corollary matters as much as the rule: while submissions to DOJ now constitute self-disclosures for purposes of both DOJ and HHS-OIG, and for both criminal and civil matters, a submission to HHS-OIG on its own generally will not qualify as a voluntary self-disclosure under the CEP or support a declination, although it may still earn cooperation and remediation credit.[\[21\]](#) The joint policy itself did not address civil FCA exposure, but DOJ's Civil Division supplied that piece one week later, as discussed below.

Deputy Assistant Attorney General (DAAG) Jacob Foster, who oversees the DOJ Fraud Division's Health Care Fraud Section, speaking at the STAT Summit in Boston, positioned the change as removing uncertainty for industry, which, he said, should not have to ask, "What do you do? Who do you call?"[\[22\]](#) DAAG Foster also stressed that DOJ is using artificial intelligence, whistleblowers, and its own data to find fraud, and warned that companies that wait may lose the chance to come forward with a voluntary self-disclosure.

The Civil Counterpart: The FCA Self-Disclosure Pilot

One week after the joint criminal policy, on October 22, 2026, DOJ's Civil Division and HHS launched a six-month Healthcare False Claims Act Self-Disclosure Pilot Program (FCA SDPP).[\[23\]](#) The pilot, developed with HHS' Office of the General Counsel, HHS-OIG, and the Centers for Medicare & Medicaid Services (CMS), offers a coordinated resolution of civil liability under the FCA and of certain HHS administrative authorities, namely Medicare enrollment revocation and HHS-OIG's permissive exclusion authorities for false claims and for fraud and kickbacks.[\[24\]](#) Companies submit disclosures by email to FCA-SDPP@usdoj.gov, and the window closes on April 22, 2027; DOJ will not review late or incomplete submissions.[\[25\]](#)

The pilot is open to providers, suppliers, manufacturers, payers, and related entities paid directly or indirectly by HHS federal health care programs, but only for potential FCA violations not already known to the government. A company whose conduct is already on the government's radar may still earn disclosure and cooperation credit

Copyright 2026, American Health Law Association, Washington, DC. Reprint permission granted.

under Justice Manual § 4-4.112, but it cannot resolve the matter through the pilot. A complete submission must describe the conduct, attach documents sufficient to show how the conduct operated, describe remediation, provide the financial information DOJ needs to calculate a “Base Self-Disclosure Repayment,” and include a certification of truthfulness and completeness from an authorized company representative.[\[26\]](#)

The benefits are concrete. The company repays 1.25 to 1.6 times the base amount, with the multiplier set by factors such as the timeliness of the disclosure, the duration and scope of the conduct, senior leadership involvement, the financial benefit to the company, and whether the company inherited the conduct through an acquisition and properly remediated it. In return, the company receives an FCA release with no factual admissions; HHS-OIG will not require a corporate integrity agreement; CMS will not impose civil monetary penalties or seek revocation; and no separate disclosure is required under the HHS-OIG SDP or the CMS Self-Referral Disclosure Protocol, among other things.

The two programs are built to fit together. Potentially criminal conduct must still be disclosed to the Fraud Division, and when a company makes a CEP-qualifying disclosure they need not file a duplicate submission with the Civil Division, which will request documentation only as need to provide a civil release.[\[27\]](#) Assistant Attorney General Brett A. Shumate framed the pilot as a way to resolve matters with companies that accept responsibilities while concentrating Civil Division resources, in partnership with whistleblowers, on those that do not.[\[28\]](#) For in-house legal and compliance teams, the map is now considerably clearer: potentially criminal conduct goes to the Fraud Division; civil FCA exposure may be resolved through the FCA SDPP while the pilot remains open, and HHS-OIG’s SDP remains available for civil and administrative matters outside the pilot.

The Decision to Disclose: A Careful Balance

Whether to self-disclose remains both a legal and business assessment, not a reflex. On the business side, management must consider the business’s operations; its relationships with patients, payers, and partners; its reputation; and its long-term strategy. Legal and compliance leaders, working with outside counsel, *must* also concurrently weigh several critical legal considerations which, depending on the facts, may override business considerations:

- **Degree of legal risk.** Is the conduct potentially criminal, or better resolved civilly or administratively? Is the conduct ongoing, or has it been remediated?
- **Timing.** The CEP requires disclosure reasonably promptly and before an investigation is imminent. Credit can erode while a company deliberates. The FCA SDPP adds a hard deadline: it accepts submissions only through April 22, 2027.

- **Likelihood of independent detection.** Data analytics, whistleblower incentives that reach even culpable insiders, and qui tam relators all raise the odds of government detection.[\[29\]](#)
- **Collateral consequences.** Exclusion, FCA liability, and obligations to payers and partners may follow any disclosure. The FCA SDPP, however, now offers a path to resolve FCA, exclusion, and Medicare revocation exposure together for qualifying civil matters.

These factors often pull in different directions. The October 15 and October 22 announcements change where a disclosure is made and what a company can expect in return, but do not alter the need to weigh those risks thoughtfully and deliberately with counsel.

Proactive Risk Exposure Assessments to Begin Now

The best way for a company to preserve its options in the event of a potential civil or criminal violation is for it to understand its risks before the government does. That work belongs to legal and compliance, but it depends on the business functions that hold data that could reveal a potential violation. Teams can undertake several steps now:

- **Know your data.** DOJ and HHS-OIG are closely scrutinizing publicly available health care data from all angles. Legal and compliance departments should partner with revenue cycle, internal audit, and data analytics teams to take a 360-degree view: billing and coding outliers, referral relationships, customer and patient complaints, hotline reports, negative audit findings, and items flagged in risk assessments.
- **Screen early for criminal exposure.** At FDA-regulated companies, regulatory affairs, quality, and pharmacovigilance teams are essential partners on FDCA risk, including adverse event reporting, misbranding, adulteration, and current good manufacturing practice deficiencies; ExThera and Kimberly-Clark show how those failures become criminal cases. Commercial and sales operations leaders should also be engaged on Anti-Kickback Statute risk.
- **Update disclosure protocols.** Legal departments should revise escalation procedures that default to HHS-OIG and revisit pending SDP matters for potential criminal exposure, and evaluate whether civil-only matters qualify for the FCA SDPP before its April 22, 2027 deadline.
- **Strengthen internal reporting.** Compliance and human resources should give employees a credible channel and a prompt response, given new incentives to report externally.
- **Document remediation as it happens.** Root-cause analysis, discipline, and control enhancements carry the most weight when recorded contemporaneously.
- **Keep the board informed.** Regular reporting to the audit or compliance committee lets leadership act quickly if a disclosure decision arises.

DOJ has built a larger, faster, and more data-driven health care fraud program and has now given companies clear front doors, criminal and civil. In-house legal and compliance teams that understand their company's exposure today will be best positioned to make a sound decision, on their own timeline, if a problem surfaces.

About the Authors

Kevin Lowell is a Member in Miller & Chevalier's Litigation department, where he represents clients in high-stakes litigation, government investigations and enforcement actions, and white collar defense, with an emphasis on health care fraud, False Claims Act (FCA) litigation, and regulatory enforcement. He joined Miller & Chevalier after more than a decade at the U.S. Department of Justice (DOJ), where he most recently served as Deputy Chief of the National Fraud Enforcement Division, Health Care Fraud Section. A first-chair trial lawyer, he led some of the government's most complex investigations. Kevin draws on his DOJ experience to guide clients through government matters, from initial risk exposure through resolution, including subpoenas, internal investigations, and trial when needed, as well as compliance program design and implementation.

Bradley Markano is a Counsel in Miller & Chevalier's Litigation department. Bradley is a skilled litigator whose practice focuses on high stakes commercial and class action litigation, with particular expertise in cases brought under the False Claims Act and state consumer fraud statutes. As part of the firm's Complex Civil Litigation and White Collar Defense practices, Bradley has handled all stages of multi-jurisdictional investigations and litigation, including pre-complaint investigations, motions practice, discovery, trial, and appeals. He has made appearances in state and federal courts nationwide.

Mena Sawyer is an Associate in Miller & Chevalier Litigation department, where she focuses on business and human rights, complex civil litigation, white collar defense, and internal investigations. Mena earned her J.D. from Howard University School of Law where she was a Dean's Fellow, a Student Attorney in the Estate Planning and Heirs' Property Clinic, and a member of the Huver I. Brown Trial Advocacy Team. She was also a member of Howard's Alternative Dispute Resolution Consortium.

[1] U.S. Dep't of Justice, Nat'l Fraud Enf't Div. & U.S. Dep't of Health & Hum. Servs., Off. of Inspector Gen., *Policy on Coordination of Voluntary Self-Disclosure in Health Care Fraud Matters* (Oct. 15, 2026), <https://www.justice.gov/opa/media/1466291/dl?inline>.

[2] Press Release, *U.S. Dep't of Justice, 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>.

[3] U.S. Dep't of Justice, Crim. Div., Fraud Section, *Year in Review 2025*, <https://www.justice.gov/criminal/media/1425226/dl> (describing the Health Care Fraud Unit's 2025 corporate resolutions as its first in nearly a decade).

[4] Press Release, U.S. Dep't of Justice, *Troy Health, Inc. Enters Non-Prosecution Agreement and Admits Fraudulently Enrolling Medicare Beneficiaries* (Aug. 20, 2025), <https://www.justice.gov/opa/pr/troy-health-inc-enters-non-prosecution-agreement-and-admits-fraudulently-enrolling-medicare>.

[5] Press Release, U.S. Dep't of Justice, *Kimberly-Clark Corporation to Pay \$40M to Resolve Criminal Charge Related to Sale of Adulterated Surgical Gowns* (Aug. 28, 2025), <https://www.justice.gov/opa/pr/kimberly-clark-corporation-pay-40m-resolve-criminal-charge-related-sale-adulterated>.

[6] Fraud Section, *Year in Review 2025*, *supra* note 3.

[7] Press Release, U.S. Dep't of Justice, *Former ExThera Medical Corporation Executive Admits to Concealing Patient Deaths from FDA and Company Enters Deferred Prosecution Agreement* (Mar. 5, 2026), <https://www.justice.gov/opa/pr/former-exthera-medical-corporation-executive-admits-concealing-patient-deaths-fda-and>.

[8] Press Release, U.S. Dep't of Justice, *Fraud Division Resolves Fraud Investigation of Eye Care Group Under New Corporate Enforcement Policy* (July 29, 2026), <https://www.justice.gov/opa/pr/fraud-division-resolves-fraud-investigation-eye-care-group-under-new-corporate-enforcement>.

[9] Press Release, *supra* note 2.

[10] Memorandum from Colin M. McDonald, Assistant Att'y Gen., Nat'l Fraud Enf't Div., *The Fraud Division's Enforcement Priorities* (Aug. 13, 2026).

[11] Press Release, *supra* note 2; Miller & Chevalier, *Full Speed Ahead: DOJ's Fraud Division Accelerates Its Corporate Enforcement Agenda* (Oct. 6, 2026), <https://www.millerchevalier.com/publication/full-speed-ahead-doj-s-fraud-division-accelerates-its-corporate-enforcement-agenda>.

[12] Directive 26-12, Colin M. McDonald, Assistant Att'y Gen., *Corporate Enforcement in the Fight Against Fraud* (Oct. 1, 2026), <https://www.justice.gov/opa/media/1463571/dl?inline>.

[13] Publication of the OIG's Provider Self-Disclosure Protocol, 63 Fed. Reg. 58399 (Oct. 30, 1998), <https://www.govinfo.gov/content/pkg/FR-1998-10-30/html/98-29064.htm>; U.S. Dep't of Health & Hum. Servs., Off. of Inspector Gen., *Health Care Fraud Self-Disclosure Protocol* (updated Oct. 15, 2026), <https://oig.hhs.gov/documents/self-disclosure-info/11951/hhs-oig-self-disclosure-protocol.pdf>.

[14] U.S. Dep't of Justice, Justice Manual § 9-28.000, Principles of Federal Prosecution of Business Organizations.

[15] Memorandum from Matthew R. Galeotti, Head of the Crim. Div., *Focus, Fairness, and Efficiency in the Fight Against White-Collar Crime* (May 12, 2025), <https://www.justice.gov/criminal/media/1400046/dl> (directing revisions to the Criminal Division Corporate Enforcement and Voluntary Self-Disclosure Policy).

[16] U.S. Dep't of Justice, *Corporate Enforcement and Voluntary Self-Disclosure Policy* (Mar. 10, 2026), <https://www.justice.gov/dag/media/1430731/dl?inline>.

[17] Joint Policy, *supra* note 1, at 1.

[18] Press Release, *supra* note 4; Letter Agreement Between U.S. Dep't of Justice and Troy Health, Inc. ¶ 2 (Aug. 14, 2025), <https://www.justice.gov/criminal/media/1411396/dl>.

[19] Joint Policy, *supra* note 1; Press Release, *supra* note 2.

[20] Press Release, *supra* note 2.

[21] Joint Policy, *supra* note 1, at 4.

[22] Isabella Cueto, *The Trump Administration Is Doubling Down on Health Care Fraud Investigations*, STAT (Oct. 15, 2026), <https://www.statnews.com/2026/10/15/healthcare-fraud-new-doj-policy-rewards-self-disclosure/>.

[23] Press Release, U.S. Dep't of Justice, *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>.

[24] U.S. Dep't of Justice & U.S. Dep't of Health & Hum. Servs., *Healthcare Self-Disclosure Pilot Program § I* (Oct. 22, 2026), <https://www.justice.gov/opa/media/1467546/dl> (FCA SDPP Protocol).

[25] *Id.* § II; Press Release, *supra* note 23.

[\[26\]](#) FCA SDPP Protocol, *supra* note 24, § II.

[\[27\]](#) Press Release, *supra* note 23, at n.1; FCA SDPP Protocol, *supra* note 24, at 1 n.1.

[\[28\]](#) Press Release, *supra* note 23.

[\[29\]](#) Directive 26-12, *supra* note 12; Miller & Chevalier, *supra* note 11.