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Memorandum

DOJ's National Fraud Enforcement Division Health Care Fraud Priorities and Self-Disclosure Considerations

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The U.S. Department of Justice ("DOJ") National Fraud Enforcement Division's (the "Fraud Division") recent Directive 26-12 on corporate enforcement prioritized both health care fraud and violations of the Federal Food, Drug, and Cosmetic Act ("FDCA"). DOJ's focus on health care and FDA-regulated products heightens the need for companies to review their compliance and monitoring programs and the information generated by such programs in a timely manner. Once misconduct is identified, health care and life sciences companies must decide whether to self-disclose such conduct under the DOJ's Corporate Enforcement and Voluntary Self-Disclosure Policy, knowing that DOJ has increased incentives to whistleblowers to report health care fraud. Below, we highlight key takeaways, the Fraud Division's recent enforcement actions, and considerations for companies evaluating whether to self-disclose potential violations.

Key Takeaways

- **DOJ Has Additional Data and Resources to Combat Health Care Fraud**: In addition to working with whistleblowers, the Fraud Division is using artificial intelligence, advanced analytics, Centers for Medicare & Medicaid Services ("CMS") claims, and other CMS beneficiary and provider data; generating leads through its National Fraud Detection Center; and entering into agreements with the Federal Trade Commission and Department of Homeland Security to proactively identify misconduct and improve access to information needed to identify health care fraud. The Fraud Division is also offering new incentives to whistleblowers of between $10,000 to $30,000 in up-front awards for tips that lead to criminal charges, increasing the risk that misconduct will be reported to the government through an individual before a company may access the protections that DOJ offers through voluntary self-disclosure.
- **DOJ Encourages Self-Disclosure of Misconduct**: DOJ's Corporate Enforcement and Voluntary Self-Disclosure Policy ("CEP") is designed to encourage companies to voluntarily self-disclose, cooperate, and remediate misconduct. The CEP enables DOJ to decline to prosecute a company for criminal conduct if certain factors are satisfied, such as the company's voluntary self-disclosure of the misconduct to DOJ as soon as reasonably practicable and within 120 days of receiving a whistleblower's internal report, full cooperation with the DOJ investigation, timely and appropriate remediation, and a lack of aggravating circumstances. Despite such incentives, a company's decision to voluntarily self-disclose can be multifaceted.

The Fraud Division's Health Care and FDA Priorities

Under an August 2026 DOJ final rule, the Fraud Division was assigned criminal proceedings (1) involving fraud or abuse with respect to health plans and (2) relating to health care fraud and controlled substances distribution and diversion schemes. The rule authorizes the Fraud Division to seek injunctions against fraud, obtain restitution, seize or forfeit property, recover penalties, and prosecute criminal offenses identified during investigations.[1]

The recent DOJ Directive 26-12 addressing corporate enforcement instructed Fraud Division prosecutors to prioritize the health care industry, including health care fraud, distribution of controlled substances, and violations of the FDCA. DOJ's focus on FDCA violations could capture FDA-regulated products as well as companies involved in product marketing, manufacturing, and regulatory submissions. The Fraud Division's health care enforcement priorities also include fraud in telemedicine, Medicare and Medicaid fraud, controlled substances diversion, home health and hospice fraud, day care and special services health care fraud, and deceptive marketing of unsafe products and services.

Example DOJ Enforcement Actions

Directive 26-12 lists ten factors on which prosecutors must place "great weight" in deciding whether to charge a company and in negotiating plea or other agreements, including: knowledge of or involvement in the scheme by corporate management; efforts to conceal fraud from government agencies or auditors; conduct lasting three years or more; actions that threaten the safety or security of Americans; conduct affecting three or more federal districts; and conduct resulting in financial harm to 25 or more victims or $25 million or more in loss. Companies should ensure compliance programs, internal controls, and monitoring tools consider these factors. Below, we discuss a few recent DOJ enforcement actions related to healthcare and FDA-regulated products.

On November 6, 2026, DOJ settled two cases for over $14.25 million; the cases involved laboratories that allegedly paid kickbacks to marketers, health care providers, and health care executives in the form of masked commission payments and exclusive entertainment events. On October 22, 2026, DOJ announced a Los Angeles health care fraud takedown charging 15 defendants, including six health care professionals, for sham substance abuse treatment claims of over $1.6 billion, as well as $134 million in Medicare billing for unnecessary arterial procedures that injured patients (which were identified through data analytics showing the surgeon was an extreme billing outlier). DOJ also charged several individuals for operating fraudulent hospice schemes and unnecessary hospice services, for kickbacks associated with unnecessary genetic testing orders and referrals to clinical treatment facilities, and for arranging for fraudulent prescriptions for medically unnecessary medications during a period where California's Medi-Cal suspended its prior authorization requirement before such medications could be provided.

Earlier, on June 23, 2026, DOJ's National Health Care Fraud Takedown resulted in charges against 455 defendants, including 90 doctors and other health care professionals, in connection with over $6.5 billion in

[1] Establishing the National Fraud Enforcement Division, 91 Fed. Reg. 53357 (Aug. 18, 2026) (codified at 28 C.F.R. pt. 0).

alleged false claims. This takedown included charges against individuals for fraudulent claims associated with amniotic wound allografts, behavioral health services that were not provided, hospice fraud involving patients who were not terminally ill, and social adult day care services that were not medically necessary.

Self-Reporting Policies

Fraud Division prosecutors follow the CEP, which applies to all corporate criminal matters handled by DOJ and establishes three tiers of outcomes based on company self-reporting and other factors. Under Part I of the CEP, DOJ will decline to prosecute a company that voluntarily self-disclosed, fully cooperated, and appropriately remediated absent aggravating circumstances (such as egregious or repeated conduct causing severe harm), subject to prosecutor discretion. A company must still pay disgorgement and restitution, and declinations are made public. If a company's self-report falls short of receiving Part I treatment, or aggravating circumstances exist, under Part II of the CEP, a company will generally receive a non-prosecution agreement for a term of three years or less, no compliance monitor requirement, and a 50% to 75% reduction off the low end of the penalty range in the applicable sentencing guidelines. If a company is not eligible for treatment under Parts I or II, then Part III of the CEP provides prosecutorial discretion for other resolutions, but limits reductions of monetary penalties to no more than 50%.

Under the CEP, a qualifying voluntary self-disclosure must be made in good faith to the appropriate DOJ component, concern misconduct not previously known to DOJ, occur before an imminent threat of disclosure or investigation, and be reasonably prompt, with the burden on the company to show timeliness. Disclosures made only to regulators or civil enforcement agencies generally do not qualify. Where a whistleblower reports both internally and to DOJ, a company can still qualify by self-reporting within 120 days of the whistleblower's internal report. Cooperation credit starts at zero and must be earned, and remediation requires, among other things, a root cause analysis and an effective compliance program.

On October 15, 2026, the Fraud Division's Health Care Fraud Section and the U.S. Department of Health and Human Services Office of Inspector General ("HHS OIG") issued a joint policy addressing where companies should disclose potential health care fraud. The policy recognizes that a single course of conduct—such as an illegal remuneration arrangement or a scheme to bill for medically unnecessary services—frequently gives rise to overlapping criminal, civil, and administrative matters, so that a company that decides to disclose must also decide to which governmental entity it will disclose. Under the joint policy, a qualifying CEP self-disclosure to the Fraud Division (or other Department of Justice components, such as a U.S. Attorney's Office) involving a federal health care program will also receive the benefits of HHS OIG's Health Care Fraud Self-Disclosure Protocol ("SDP"), which include accelerated resolution, a lower penalty multiplier, and an exclusion release, without a separate SDP submission.

Conversely, a disclosure made only to HHS OIG under the SDP generally will not qualify as a voluntary self-disclosure under the CEP, although it may be credited as cooperation and remediation. HHS OIG's October 2026 version of the SDP states that it "is not available for CEP disclosure of Federal crimes," which should be disclosed to DOJ. Companies with potential criminal exposure should now disclose to the Fraud Division first to preserve eligibility for both sets of benefits.

Considerations for Those Contemplating Self-Reporting

Health care and life sciences companies contemplating whether to self-disclose misconduct should consider the following in light of the Fraud Division's health care and FDCA priorities:

- **Decide where to self-disclose.** Companies seeking the benefits of both the CEP and the HHS OIG SDP should make their initial disclosure of potential criminal conduct to the Fraud Division (or other Department of Justice components, such as a U.S. Attorney's Office), as an SDP-only submission will generally foreclose a CEP Part I declination.
- **A single disclosure will not resolve all exposure.** Disclosure to the Fraud Division does not automatically resolve civil liability under the False Claims Act, and whistleblowers may still file *qui tam* suits. A company seeking a False Claims Act release must expressly ask DOJ to resolve that liability, as HHS OIG cannot release those claims. Companies should expect SDP resolutions to exceed single damages and should evaluate the civil or criminal nature of the conduct before disclosing, since the SDP covers only conduct subject to civil monetary penalties.
- **Timing matters.** Because the Fraud Division is generating leads through the National Fraud Detection Center and is incentivizing whistleblowers, companies that identify potential misconduct may have a narrower window to self-report before the government learns of the conduct independently. Companies should have escalation protocols in place to evaluate potential issues promptly.
- **Assess the conduct against the Fraud Division's aggravating factors.** In evaluating whether to self-report, companies should consider whether the conduct implicates the factors Directive 26-12 identifies for "great weight", which increase the likelihood of enforcement and the potential value of early disclosure.
- **Expect coordinated, multi-agency exposure.** DOJ's Civil Division has designated a Fraud Division liaison to leverage civil and criminal tools, and the 2026 Takedown was accompanied by CMS payment suspensions and revocations, HHS OIG exclusions, Civil Monetary Penalties Law actions, and Drug Enforcement Administration administrative actions. Companies weighing self-disclosure should consider potential civil, administrative, and state-level consequences alongside criminal exposure.

Additional Considerations for Life Sciences Companies

- **Update compliance programs.** Given the express focus on FDCA violations and companies that deceive regulators or deceptively market unsafe products, life sciences companies should review compliance programs on promotional practices, manufacturing and quality, and regulatory submissions, in addition to anti-kickback and billing controls.
- **Emerging risks such as prediction markets also warrant attention**. The creation of prediction markets for clinical trial outcomes and FDA decisions invites risk, including patient harm and the disclosure of confidential, nonpublic information. Since clinical trial results and FDA communications may be material nonpublic information in insider trading cases, prediction markets risk moving trades on confidential information into a less-regulated venue. The number of trial stakeholders (site personnel, patients, government employees and contractors, and company employees) who have access to clinical trial information makes such information difficult to safeguard. Prediction platforms may also create risks for trial integrity; patients may react to market signals by dropping out of studies and participants may affect or manipulate outcomes. We recommend life sciences companies adopt policies tailored to these risks and to capture broad sources of potential fraud.

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