Department of Justice and Department of Health and Human Services Healthcare Self-Disclosure Pilot Program

I. Background

The Department of Justice (DOJ) and the Department of Health and Human Services (HHS) have long encouraged the healthcare industry to proactively invest in compliance and transparently engage with the government. Building on long-standing efforts to incentivize voluntary self-disclosures, DOJ Civil Division and HHS (Office of the General Counsel, Office of the Inspector General (OIG), and the Centers for Medicare & Medicaid Services) are launching a healthcare self-disclosure pilot program (FCA SDPP) to offer a clear and predictable pathway for companies seeking to obtain a coordinated resolution of civil liability under the federal False Claims Act (FCA), 31 U.S.C. § 3729 et seq., and the following HHS administrative authorities: 42 C.F.R. §§ 424.535 (Revocation of enrollment in the Medicare program), 1001.901 (Permissive exclusion for false or improper claims), and 1001.951 (Permissive exclusion based on fraud and kickbacks or other prohibited activities).[1]

This pilot program supports legitimate American healthcare businesses endeavoring to quickly and cooperatively resolve prior misconduct and move forward with a clean slate. The program is not for illegitimate businesses that knowingly exploit the generosity of the American people through various fraudulent schemes.

II. Eligibility Criteria

Healthcare providers, suppliers, manufacturers, payors, and related entities that furnish, arrange for, manufacture, distribute, insure, administer, or bill for items or services reimbursed, subsidized or otherwise paid for, directly or indirectly, by HHS Federal health care programs (disclosing company) are eligible to participate in this pilot program.

The self-disclosure submission must disclose a potential violation of the FCA previously unknown to the federal government. If the federal government was already aware of the potential violation of the FCA, the disclosing company shall be eligible for self-disclosure and cooperation credit pursuant to Justice Manual Section 4-4.112 but shall not be eligible for a resolution pursuant to this pilot program.

[1] The FCA SDPP is a pilot program available for conduct that potentially violates civil laws. A company seeking to self-disclose potential criminal conduct related to health care must disclose that conduct to the Justice Department's National Fraud Enforcement Division pursuant to the National Fraud Enforcement Division and HHS-OIG Policy on Coordination of Voluntary Self-Disclosure in Health Care Fraud Matters. A company that makes a voluntary self-disclosure of criminal matters to the Fraud Division within the meaning of the CEP need not make a duplicative submission to FCA-SDPP@usdoj.gov. Where a company also seeks a civil FCA release through the FCA SDPP, supplementation of its Fraud Division disclosure will be requested only to the extent necessary.

Disclosing companies must submit a self-disclosure by 11:59 PM on April 22, 2027 to FCA-SDPP@usdoj.gov. Late or partial submissions will not be accepted or reviewed.

The self-disclosure shall:

- Describe all relevant details relating to the disclosing company's conduct that, in the disclosing company's reasonable assessment, potentially violate the FCA ("disclosed potential FCA violations"), including the specific laws, regulations, or other binding requirements that were violated and the time period of the violations.

- Append as exhibits all documents sufficient to fully reflect the nature, terms, and operation of the disclosed potential FCA violations. The disclosing company's written description of the disclosed potential FCA violations should cross-reference the exhibits.

- Specify the remedial measures or other corrective action the disclosing company has taken to terminate the disclosed potential FCA violations and prevent them from reoccurring. Examples of potentially responsive remedial measures are cited in Justice Manual Section 4-4.112.

- Provide financial information sufficient to facilitate the DOJ Civil Division calculating the Base Self-Disclosure Repayment. DOJ and HHS reserve the right to request supplemental information as necessary.

- Include a certification from the disclosing company's authorized representative stating that to the best of the individual's knowledge, the submission contains truthful and complete information about the disclosed potential FCA violations.

- Include the phone number and email address of the disclosing company's designated point of contact for purposes of any follow-up questions relating to the self-disclosure (which may, but does not need to be, the certifying authorized representative).

III. Benefits of Disclosure

- Coordinated civil release

The disclosing company will receive favorable treatment from DOJ Civil Division and HHS in a coordinated civil release, with no factual admissions.

In particular, the disclosing company shall receive a release from the DOJ Civil Division under the federal FCA for the disclosed potential FCA violations. Consistent with the HHS OIG Health Care Fraud Self-Disclosure Protocol, HHS OIG shall not require a Corporate Integrity Agreement as part of any resolution of HHS OIG's exclusion authorities under this pilot program. CMS shall not impose civil monetary penalties or seek revocation as part of any resolution under this pilot program. Disclosing parties need not make any other self-disclosures of the same conduct to any other applicable existing civil self-disclosure

programs, such as the HHS-OIG Health Care Fraud Self-Disclosure Protocol or the CMS Self-Referral Disclosure Protocol.

- Favorable financial resolution

The financial repayment shall be 1.25–1.6 times the amount of the Base Self-Disclosure Repayment. The multiplier applied will vary based on factors such as the timeliness of the self-disclosure, the duration and scope of the misconduct, the involvement of the company's senior leadership, the financial benefit to the disclosing company, and whether the disclosing company has successor liability for the misconduct but promptly remediated.

Sample Base Self-Disclosure Repayment Calculations

Example 1: A hospital realizes it had not been complying with Medicare's 14-day rule (42 C.F.R. § 414.510) and identifies instances of the hospital delaying submission of physician lab orders to circumvent the 14-day rule. The hospital conducts a sample chart review covering the relevant time period and identifies an error rate, which it extrapolates over the population of claims to calculate a Base Self-Disclosure Repayment. The hospital produces the chart review results and information about the sampling and extrapolation methodologies for the government's review.

Example 2: A company acquires a healthcare company. The acquiring company discovers post-close that the legacy company had engaged in conduct that the acquiring company believes may establish FCA liability through a potential violation of the AKS. The acquiring company produces documentation of the payments and the associated revenue for the government's review. Although courts have determined that the amount of remuneration or the revenue derived in kickback schemes are generally not consistent with the damages incurred by the United States, for the limited purpose of this pilot program, the government will forego damages based on the claim-paid amounts and instead calculate the Base Self-Disclosure Repayment for Anti-Kickback Statute violations based on consideration of the amount of the remuneration, the revenue derived from the disclosed conduct, and the absence of aggravating factors such as patient harm.