



## Compliance with Applicable Federal and State Laws - False Claims Act and Similar Laws

**Purpose**

The purpose of this policy (“Policy”) is to provide information regarding:

- the federal and state False Claims Acts (“FCA”),
- related administrative remedies for false claims and statements, and other state laws that provide for legal sanctions in connection with making false claims or statements (collectively, the “Acts”),
- protections for individuals who in good faith report under such laws, and
- Fresenius’ commitment to detecting and preventing fraud, waste and abuse in federal and state health care programs.

The requirements set forth in this policy are intended to satisfy Section 6032 of the Deficit Reduction Act of 2005 (“DRA”)(codified at section 1902(a)(68) of the Social Security Act), and related state requirements.

**Applicable Parties**

This Policy applies to all Fresenius employees, and to contractors and agents, as defined below, in those states for which DRA Section 6032 applies to Fresenius’ business operations.

**Policy**

- Fresenius is committed to complying with all applicable federal and state laws, including laws prohibiting the submission of false claims and statements.
- Fresenius disseminates information to its employees, contractors and agents regarding the Acts, whistleblower protections under such laws, related administrative remedies, and Fresenius’ commitment to detecting and preventing fraud, waste and abuse in federal and state health care programs.
- All Fresenius employees must adhere to this Policy and Fresenius expects that its relevant contractors and agents will follow the principles described in this Policy to the extent they are relevant and applicable to the contractors’ or agents’ interactions with Fresenius.

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**Federal False Claims Act**

The federal FCA (31 U.S.C. §§ 3729-3733) is a civil law aimed at preventing fraud against the government, including fraudulent billing and fraudulent submission of claims or statements to any Federal health care program (e.g., Medicare and Medicaid). Specifically, the FCA prohibits any person or entity (including dialysis facilities, clinical laboratories, and physicians) from, among other things:

- Knowingly presenting, or causing to be presented, to the government a false or fraudulent claim for payment or approval (i.e., submitting a claim to Medicaid which is known to have wrong information);
- Knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government (i.e., signing a certification claiming that the information being submitted is correct, yet the individual signing knows it is not correct);
- Conspiring to defraud the government by getting a false or fraudulent claim allowed or paid (i.e., working with or planning with another party to get a fraudulent claim paid by Medicaid); and
- Knowingly making, using or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the government (often referred to as a “reverse false claim”).

For health care providers and suppliers, the FCA most directly applies when a false claim for reimbursement is submitted for payment to a government program, such as Medicare or Medicaid, and the provider knew or should have known the information or certification on the claim was false. The U.S. Department of Justice (“DOJ”) has authority to bring a FCA action and must file a complaint to initiate such an action.

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**Essential Elements of the FCA**

To successfully establish a cause of action under the FCA, the government must prove the following elements:

**1. Intent:** The entity or individual submitting (or causing someone else to submit) the false claims or statements must do so knowingly. The term “knowingly” under the False Claims Act means the person:

- has actual knowledge of the falsity of the information;
- acts in deliberate ignorance of the truth or falsity of the information; or
- acts in reckless disregard of the truth or falsity of the information.

**2. False Claim:** There must be a false “claim” submitted or presented to the federal government. A claim includes any request or demand for if the government provides any portion of the money that is requested or demanded, or if the government will reimburse for any portion of the money requested or demanded.

**3. Materiality:** Many courts also require as part of a FCA lawsuit that the false information or claim was material (a factor) to the government’s decision to make payment.

**Timeframe for Bringing a Claim**

A civil suit may be brought either: (1) three years after the violation was discovered by the responsible federal official (but no more than 10 years after the violation was committed), or (2) six years after the violation was committed, whichever is later.

**FCA Damages and Penalties**

If the defendant (*i.e.*, health care provider that submitted a false claim to Medicare) is found by a court to have violated the FCA, the court is authorized to award three times the amount of damages to the government (often referred to as “treble damages”) plus penalties of \$5,500 to \$11,000 for each false claim.

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**Administrative Remedies**

The government may pursue false claims violations using the FCA or other laws and enforcement tools, including administrative remedies.

- Other Federal administrative laws include the Program Fraud Civil Remedies Act (“PFCRA”), which allows for the United States to recover penalties of up to \$5,000 per false claim or statement and potentially up to twice the amount of the claim or portion of the claim determined to be in violation of law.
- The U.S. Department of Health and Human Services Office of Inspector General (“OIG”) has an administrative civil penalty authority called the Civil Monetary Penalties Law (“CMPL”), which authorizes the OIG to seek three times the amount claimed plus up to \$10,000 per false claim. OIG may use the CMPL authority to go after false claims if DOJ authorizes such use following a decision not to pursue the matter under the FCA.
- The OIG may also seek to exclude an entity or person from participating in Medicare and Medicaid for conduct that violates the FCA. Such an exclusion prohibits the person or entity from participation in any federal health care program.

**State False Claims Acts**

A number of states have enacted false claims act legislation that mirrors or closely resembles the federal FCA. For those states that have not yet enacted a specific false claims act, other criminal and civil laws, including health care fraud laws and other anti-fraud laws that relate to state Medicaid programs, may be used to prosecute health care fraud involving the wrongful submission of false claims and/or false statements used to obtain state health care program funds.

For information about the false claims act or other applicable law in the state in which you work, please refer to the state-by-state chart of relevant laws included with the DRA Resources, which are incorporated by reference into this Policy.

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**Employee Protections**

In accordance with federal law, certain state laws, and Fresenius policy, employees, who in good faith report actual or suspected violations of law, regulation or policy, may not be discharged, demoted, suspended, threatened, harassed or discriminated against by his or her employer in the terms of his or her employment based on lawful acts done by the employee in furtherance of an action under the false claims act law. Remedies for such retaliation under the applicable laws may include reinstatement with comparable seniority the employee would have had but for the discrimination, two times the amount of back pay, interest on back pay, or payment for special damages sustained as a result of the discrimination. For additional information on employee protections, see the state false claims act summaries, as well as Fresenius' policies and procedures regarding non-retaliation and reporting

**Detecting and Preventing Fraud, Waste and Abuse**

Fresenius has an established health care compliance program that includes, among other initiatives, regular education, an employee hotline, written policies and procedures, regular audits and reviews, and employee and contractor screening. Fresenius' policies specifically address Fresenius' ongoing efforts to detect and prevent waste, fraud and abuse in federal and state health care programs. Copies of these policies and procedures are available to all Fresenius employees through the Fresenius intranet. Additionally, employees receive training on the compliance program on an annual basis. Contractors and agents also have access to copies of relevant compliance program policies and procedures to detect and prevent waste, fraud and abuse and are expected to adhere to them when working on Fresenius' behalf.

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**Definitions** For purposes of this Policy, the terms “contractor” and “agent” are defined as any contractor, subcontractor, agent, or other person who, on behalf of Fresenius, furnishes or otherwise authorizes the furnishing of Medicaid health care items or services, performs billing or coding functions for Fresenius, or is involved in monitoring of health care provided by Fresenius to Medicaid recipients.

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**Questions** Any questions regarding this Policy, the FCA or state FCAs should be directed to the Fresenius Compliance Manager, or your Ethics and Compliance Officer.

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**References** Federal False Claims Act -- 31 U.S.C. §§ 3729-3733; Program Fraud Civil Remedies Act -- 31 U.S.C. Chapter 38; Civil Monetary Penalties Law -- 42 U.S.C. § 1320a-7(a); Deficit Reduction Act of 2005 -- Public Law 109-171 § 6032 (Feb. 8, 2006) (codified at 42 U.S.C. § 1396a(a)); state false claims acts, which are incorporated by reference into this Policy.

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