

U.S. Department of Justice
Office of the Deputy Attorney General

The Deputy Attorney General

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MEMORANDUM FOR: All United States Attorneys
All First Assistant United States Attorneys
All Civil Health Care Fraud Coordinators in the Offices of United States Attorneys
All Trial Attorneys in the Civil Division Commercial Litigation Section

FROM: Eric H. Holder, Jr.
Deputy Attorney General

SUBJECT: Guidance on the Use of the False Claims Act
in Civil Health Care Matters

One of the Department's most important tools in protecting the integrity of Medicare and other taxpayer-funded health care programs is the civil False Claims Act. While the broad reach and substantial damages and civil penalties under the Act make it one of the Department's most powerful tools, Departmental attorneys are obligated to use their authority under the Act in a fair and responsible manner. This is particularly important in the context of national initiatives, which can have a broad impact on health care providers across the country.

This guidance is being issued to emphasize the importance of pursuing civil False Claims Act cases against health care providers in a fair and even-handed manner, and to implement new procedures with respect to the development and implementation of national initiatives.

1. National Initiatives.

Generally, national initiatives deal with a common wrongful action accomplished in a like manner by multiple, similarly situated health care providers. National initiatives must be handled in a manner (i) that promotes consistent adherence to the Department's policies on enforcement of the False Claims Act, as well as a consistent approach to overarching legal and factual issues, (ii) while avoiding any rigid approach that fails to recognize the particular facts and circumstances of an individual case.

To achieve these objectives, the Department has instituted the following procedures:

(A) Legal and Factual Predicates.

Before alleging violations of the False Claims Act, whether in connection with a national initiative or otherwise, Department attorneys must evaluate whether the provider: (i) submitted false claims to the government, and (ii) submitted false claims (or any false statements made to get the false claims paid) with "knowledge" of their falsity, as defined in the Act. These are separate inquiries. Department attorneys shall not allege a violation of the False Claims Act unless both of these inquiries lead to the conclusion that there is a sufficient legal and factual predicate for proceeding. The following issues, among other issues, shall be considered in these determinations:

(i) Do False Claims Exist?

a. Examine Relevant Statutory and Regulatory Provisions and Interpretive Guidance. Department attorneys shall examine relevant statutory and regulatory provisions, as well as any applicable guidance from the program agency or its agents, to determine whether the claims are false. In certain circumstances, such as when a rule is technical or complex, Department attorneys should communicate with knowledgeable personnel within the program agency (e.g., the Health Care Financing Administration, TRICARE, Office of Personnel Management) concerning the meaning of the provision.

b. Verify the Data and Other Evidence. Department attorneys shall take appropriate steps to verify the accuracy of data upon which they are relying, either independently, or with the assistance of the fiscal intermediaries and carriers, the Department of Health and Human Services - Office of Inspector General, the Federal Bureau of Investigation, or another investigative agency.

c. Conduct the Necessary Investigative Steps. Department attorneys should conduct such investigative steps as are necessary under the circumstances, including where appropriate, the subpoenaing of documents and the interviewing of witnesses.

(ii) Did the Provider Knowingly Submit the False Claims?

In the event the claims are false, Department attorneys must next evaluate whether the health care provider "knowingly" submitted the false claims or "knowingly" made false statements to get the false claims paid. As set forth above, and before making this determination, Department attorneys should conduct such investigative steps as necessary under the circumstances, including where appropriate the subpoenaing of documents and the interviewing of witnesses. Under the False Claims Act, false claims and false statements are submitted "knowingly" if the provider had actual knowledge of their falsity, or acted with deliberate ignorance or reckless disregard as to their truth or falsity. While relevant factors will vary from case to case and the list below is not intended to be exhaustive, factors that must be considered are:

a. Notice to the Provider. Was the provider on actual or constructive notice, as appropriate, of the rule or policy upon which a potential case would be based?

b. The Clarity of the Rule or Policy. Under the circumstances, is it reasonable to conclude that the provider understood the rule or policy?

c. The Pervasiveness and Magnitude of the False Claims. Is the pervasiveness or magnitude of the false claims sufficient to support an inference that they resulted from deliberate ignorance or intentional or reckless conduct rather than mere mistakes?

d. Compliance Plans and Other Steps to Comply with Billing Rules. Does the health care provider have a compliance plan in place? Is the provider adhering to the compliance plan? What relationship exists between the compliance plan and the conduct at issue? What other steps, if any, has the provider taken to comply with billing rules in general, or the billing rule at issue in particular?

e. Past Remedial Efforts. Has the provider previously on its own identified the wrongful conduct currently under examination and taken steps to remedy the problem? Did the provider report the wrongful conduct to a government agency?

f. Guidance by the Program Agency or its Agents. Did the provider directly contact either the program agency (e.g., the Health Care Financing Administration) or its agents regarding the billing rule at issue? If so, was the provider forthcoming and accurate and did the provider disclose all material facts regarding the billing issue for which the provider sought guidance? Did the program agency or its agents, with disclosure of all relevant, material facts, provide clear guidance? Did the provider reasonably rely on such guidance in submitting the false claims?

g. Have There Been Prior Audits or other Notice to the Provider of the Same or Similar Billing Practices?

h. Any Other Information That Bears on the Provider's State of Mind in Submitting the False Claims.

(B) Oversight by National Initiative Working Groups.

For all current and future national initiatives, the Attorney General's Advisory Committee (AGAC) and the Civil Division shall establish a working group to coordinate the development and implementation of each initiative.

Working groups will be comprised of Assistant United States Attorneys and Civil Division attorneys with particular expertise in health care fraud. In accordance with the health care guidelines promulgated in January 1997, in appropriate instances each working group may also need to coordinate and plan the initiative with the Department's Criminal Division.

Each working group will (i) examine the initiative to ensure that a factual and legal predicate is present for the initiative prior to its implementation, (ii) prepare initiative-specific guidance and sample documents (such as legal analyses, summaries of audit data, contact letters, tolling agreements, compliance and settlement agreement language) for use in the initiative, and (iii) prepare a general investigative plan, setting forth suggested investigative steps that each office should undertake prior to proceeding. Working groups shall be responsible for coordination with law enforcement agencies, the Health Care Financing Administration, and other appropriate entities.

While the working groups shall be responsible for coordinating the overall development and implementation of national initiatives, each matter against a specific provider must be evaluated on a case-by-case basis.

(C) Use of Contact Letters in National Initiatives.

As outlined above, Department attorneys participating in national initiatives shall, in general, make initial contacts with health care providers, to resolve a case, through the use of "contact" letters. The purpose of a contact letter is to notify a provider of their potential exposure under the False Claims Act and to offer the provider an opportunity to discuss the matter before a specific demand for payment is made. In limited circumstances, where the specific facts of a situation warrant a different approach, Department attorneys may make an initial contact through other legitimate means.

The use of contact letters to make initial contact with health care providers is in

furtherance of Executive Order 12988, which obligates Department attorneys to make a reasonable effort to notify the opposing party about the nature of the allegations, and attempt to resolve the dispute without litigation if at all possible. The type of contact employed will depend on the nature of the allegations and the stage of the investigation. Regardless of the form of initial contact, Department attorneys must ensure that health care providers are afforded: (i) an adequate opportunity to discuss the matter before a demand for settlement is made, and (ii) an adequate time to respond. In addition, Department attorneys shall grant all reasonable requests for extensions of time to the extent that they do not jeopardize the government's claims. The use of statutory tolling agreements are strongly encouraged to allow providers time to respond without jeopardizing the government's claims.

2. Alternative Remedies.

After reviewing the legal and factual circumstances of a particular matter, Department attorneys shall consider other available remedies -- including administrative remedies such as recoupment of overpayments, program exclusions, and civil monetary penalties -- to determine what remedy, or combination of remedies, would be the most suitable under the circumstances. Should the recoupment of an overpayment be the most appropriate remedy, Department attorneys shall consider referring the matter to the appropriate carrier/fiscal intermediary for appropriate action.

3. Ability to Pay Issues.

Attorneys shall consider any financial constraints identified by a provider in determining a fair, reasonable and feasible settlement between the parties. Hospitals and other health care providers citing an inability to pay a specific settlement amount should be asked to present documentation in support of their stated financial condition.

4. Rural and Community Health Care Provider Concerns -- Impact on Availability of Medical Services.

When dealing with rural and community hospitals and other health care providers, Department attorneys shall consider the impact an action may have on the community being served. In determining an appropriate resolution, or deciding whether to bring an action, care must be taken to consider the community's interest in access to adequate health care along with any other relevant concerns.

5. Hospitals and Other Health Care Providers Not Represented by Counsel.

Department attorneys shall pay special attention to contacts with hospitals and other providers that choose (due to financial constraints or otherwise) to resolve claims without legal representation. Department attorneys faced with this circumstance must carefully assess every action taken to avoid even an appearance of coercion or overreaching because of the absence of opposing counsel.

6. Minimizing Burdens Imposed on Providers During Investigations.

Department attorneys also should be mindful of the ways in which our investigations and audits can disrupt and burden the day-to-day operations of providers in both a financial and practical sense. In developing and implementing an investigative plan, we should do what we can do to minimize these adverse effects, while still meeting our obligation to diligently investigate allegations of potential fraud. For example, while recognizing that certain circumstances might

warrant different approaches, Department attorneys should consider a provider's request to accept the results of an audit of a sample of claims in lieu of a complete audit.

7. Provider Assistance with the Investigation.

In determining an appropriate settlement amount, Department attorneys should consider the extent to which a health care provider has cooperated with the audit or investigation of the relevant matter.

8. Individualized Review.

The proper determination as to the use and application of the False Claims Act or other appropriate remedy requires an individualized review of each case, ensuring that each of the above factors are given full consideration

9. Review of Guidance.

In order to assure the fair and appropriate application of the False Claims Act, this guidance will be subject to review in six months.

10. Additional Information.

Questions regarding use of the False Claims Act should be referred to the Health Care Fraud Coordinator in your district, or to Robert Liles, Health Care Fraud Coordinator for the Executive Office for United States Attorneys (tel. no. 202-616-5136), or Shelley R. Slade, Health Care Fraud Coordinator for the Civil Division (tel. no. 202-307-0264).

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