

Negotiating Fraud Settlements

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Overview of Presentation

- I. Reasons Why Settlements Are Most Common and Preferred Approach**
- II. Theories of Government Liability**
- III. Strategies, Tactics and Considerations for Settlement**

I. Reasons Why Settlements Are Most Common and Preferred Approach

- Government has a significant arsenal of laws available to: (1) prosecute individuals and companies; (2) impose penalties and fines; (3) seek exclusion; and (4) require corporate integrity agreements.
- From 1997 to present, federal, state and local government agency enforcement actions have resulted in federal health care program savings of more than \$50 billion; exclusion of more than 15,000 individuals and entities from participation in the Medicare and Medicaid programs; more than 1,500 criminal prosecutions; and more than 4,000 civil actions.

I. Reasons Why Settlements Are Most Common and Preferred Approach (Cont'd)

- Many targets of enforcement actions (both criminal and civil) have been against publicly held companies.
 - These companies typically cannot withstand publicity, and uncertainty of outcome associated with long-term litigation.
 - Since 1997, government has announced a number of high-profile, high dollar amount settlements against public companies.
- Because few companies have litigated against government in these matters, caselaw remains underdeveloped and outcome less clear.

II. Theories of Government Liability

A. False Claims Act, 31 USC §§3729-3733 (FCA)

- Biggest tool in government's arsenal against health care fraud.
- Actions brought by government or individuals acting as private attorney general on behalf of the federal government (whistleblowers or Qui Tam Plaintiffs).
- Penalties: Treble damages, civil penalties of from 5,000 to 10,000 per claim, plus the government can recover its costs of bringing the action.

II. Theories of Government Liability

A. False Claims Act (cont'd)

Civil Liability: FCA imposes civil liability on persons and entities knowingly presenting or causing to be presented false or fraudulent requests for payment or approval to the federal government. Violations may lead to civil and/or criminal penalties, as well as civil monetary penalties, federal health care program exclusion and a corporate integrity agreement.

Examples: Services not actually provided, services not medically necessary, upcoding, improper billing

II. Theories of Government Liability

A. False Claims Act (cont'd)

“Knowingly Standard” – does not require actual or specific intent, but requires actual knowledge of the falseness of the claims, acts in deliberate ignorance of the truth or falsity of the claim, or acts in reckless disregard of the truth or falsity of the claim.

II. Theories of Government Liability (cont'd)

B. Civil Monetary Penalties Law, 42 U.S.C. §1320a-7a

- Persons who among other things, present claims for payment that they know or should know are false or fraudulent, are for services that are false or fraudulent, are subject to civil monetary penalties of up to \$10,000 per item or service plus three times the amount claimed for each item or service.
 - Under 42 U.S.C. §1320a-7a(b), payments to induce reduction or limitation of services are also subject to civil monetary penalties of up to \$2,000 for each such individual with respect to whom payment is made.
 - The statute imposes civil monetary penalties on any person who is excluded from participation in Medicare or Medicaid, and who retains a direct or indirect ownership or control interest in an entity that participates, and who knows or should know of the basis for the exclusion or who is an officer or managing employee of such an entity. *See* 42 U.S.C. §1320a-7a(a)(4). The penalty imposed for such a violation is \$10,000 per each day the violation continues.
 - The statute also provides for exclusion from participation in federal health care programs.

II. Theories of Government Liability (cont'd)

C. Mandatory Exclusion Authority, 42 U.S.C. §1320a-7; 42 C.F.R. §1001.101, *et seq.*

- Under the civil monetary penalties law's implementing regulations, entities or individuals who have been convicted of Medicare/Medicaid program related crimes, and convictions of criminal offenses relating to patient neglect and abuse are subject to mandatory exclusion from participation in the Medicare/Medicaid programs for a minimum of five years, depending on the presence of certain aggravating and mitigating factors.
 - Too little care/failure to provide services are also subject to sanctions.
 - Be aware that the mandatory exclusion provision also apply to pleas of *nolo contendere*.

II. Theories of Government Liability (cont'd)

D. Permissive Exclusion Authority, 42 USC §1320a-7(b); 42 C.F.R. §1001.201. et. seq.

Even without a criminal conviction or plea under the False Claims Act, a person can be excluded from participation in federal health care programs for certain violations involving non-program related offenses, including:

- Federal or state law convictions (may be a misdemeanor) relating to fraud, theft, embezzlement, breach of fiduciary duty or other financial misconduct relating to delivery of a health care item or service.
- Failure to grant to state and federal authorities immediate access, upon reasonable request (as defined by the Secretary of the Department of Health and Human Services in regulations) to records and/or premises, as required by 42 C.F.R. §§1001, 1301.
- Convictions under state or federal law in connection with obstruction or interference with investigations.
 - Exclusion under this provision will be for three years if there are no aggravating or mitigating circumstances.

II. Theories of Government Liability (cont'd)

E. Anti-Kickback Statute; 42 USC §1320a-7b

- Prohibits the knowing and willful solicitation, receipt, offer or payment of remuneration to induce referral of items or services which may be paid for by Medicare/Medicaid or other Federal Health Care Programs. The Government may also argue that activities that violate the anti-kickback statute also violate the false claims act when claims for reimbursement are submitted.
 - Remuneration is defined broadly to include anything of value, in cash or in kind, direct or indirect. Under *U.S. v. Greber*, 760 F.2d 68 (3d Cir.), *cert denied*, 474 U.S. 969 (1985), which is controlling authority in this circuit, if even one purpose of remuneration is to induce referrals, regardless of whether there are other beneficial purposes, the statute is violated.

II. Theories of Government Liability (cont'd)

F. Ethics in Patient Referrals Act (aka the Stark Law), 42 USC §1395nn

- Prohibits physicians who have financial relationships with entities from making referrals to those entities for the furnishing of certain designated health services payable under the Medicare and Medicaid Programs.

G. Other Statutes

- The Government also uses an assortment of other statutes to pursue health care fraud, including the mail and wire fraud statutes, conspiracy, RICO, money laundering, and obstruction of justice.

III. Strategies, Tactics and Considerations for Settlement

A. Make sure you fully understand the government's allegations prior to initiating settlement discussions.

Steps Include:

- Communications with the Government determine if civil or criminal matter.
- Conducting internal investigation of the Government's claim (including compliance assessment pursuant to corporate compliance plan).
- Retain third party consultant to conduct claims review where appropriate (coordinate with Government).
- Make sure you know your client better than the Government does; need to ensure no client surprises where possible.

III. Strategies, Tactics and Considerations for Settlement (cont'd)

Additional important steps include:

- Make sure to understand the applicable statutes and regulations implicated.

Note: Mistakes are sometimes made by Government and private sector attorneys in understanding legality of underlying reimbursement issue that gives rise to the false claims allegation.

Key Point: Understanding of regulatory and reimbursement issues critical to successful comprehensive settlement.

- Failure by government attorneys and private sector attorneys to engage on the underlying substance of the allegations may result in larger settlements, in addition to hindering and delaying final settlement.
- Engaging and Settling on the alleged conduct will help to ensure the monetary amount of any settlement is related to the challenged amount at issue.

III. Strategies, Tactics and Considerations for Settlement (cont'd)

B. Make sure you know all the agencies involved, and their respective interests and issues, prior to reaching a final settlement.

- Cases often typically involve multiple federal and state agencies and working with each of them at various times during the settlement process is essential to achieving a comprehensive settlement that will serve to resolve all pending federal, state and administrative matters.
- Make sure to cover the entire applicable time period, and the entire scope of the conduct in question. Ensure release extends to CIA.
- Though federal and state agencies have coordinated much more effectively in recent years, it is still up to you to ensure a fully comprehensive settlement.

III. Strategies, Tactics and Considerations for Settlement (cont'd)

B. Make sure you know all the agencies involved, and their respective interests and issues, prior to reaching a final settlement (cont'd)

- Typical Roles/Relationships of key federal and state agencies.
 - U.S. Department of Justice
 - Main Justice (civil and criminal)
 - Local United States Attorneys Offices
 - Federal Bureau of Investigation (FBI)
 - U.S. Department of Health and Human Services
 - Office of Inspector General
 - Center for Medicare and Medicaid Services
 - Food and Drug Administration
 - State Medicaid Fraud Control Units
 - Relator or Whistleblower (FCA)

III. Strategies, Tactics and Considerations for Settlement (cont'd)

C. Make sure you have considered general legal statutory and regulatory defenses in addition to health care, regulatory and reimbursement defenses. Examples include:

- Statute of Limitations (SOL) Basic SOL is 6 years, 31 U.S.C. §3731. All claims under the FCA for alleged false claims submitted prior to the relevant six year period should be barred under the six year SOL.
- Tolling Issues Consider whether the Government will agree to extend the SOL pursuant to the FCA's tolling provision, under which the statute expires 3 years after the date when the material facts are known, or reasonably should have been known, to the responsible government officials, 31 U.S.C. §3731(a)(2).

III. Strategies, Tactics and Considerations for Settlement (cont'd)

- C. Make sure you have considered general legal statutory and regulatory defenses in addition to health care, regulatory and reimbursement defenses. Examples include (cont'd)**
- Lack of Intent Because the Government must prove intent based on the “knowing” standard under the FCA or specific intent under the anti-kickback statute, effort should be placed on showing lack of intent. Examples include:
 - Whether the health care practitioner or entity had notice of the applicable law, rule or policy.
 - Whether the health care practitioner or entity reasonably relied on proper guidance from the contractor or state agency.
 - Whether the erroneous claims were sufficient to indicate intent.

III. Strategies, Tactics and Considerations for Settlement (cont'd)

- C. Make sure you have considered general legal statutory and regulatory defenses in addition to health care, regulatory and reimbursement defenses. (cont'd)**

Health Care Defenses:

- Make sure to keep in mind the relevance of the health care regulatory/reimbursement laws and policies.
- Only statutes and regulations have legal effect or precedential impact.
- Medicare /Medicaid manual instructions and contractor bulletins are not legally binding.

III. Strategies, Tactics and Considerations for Settlement (cont'd)

D. Where possible, make sure that use of the authority is limited only to actions of that entity or individuals involved.

- Consider situation where company has multiple subsidiaries and inappropriate conduct occurred at one entity or by few individuals at entity.
 - With regard to employees, the nature of the allegations as between the company and its employees will determine whether employees should retain separate counsel.

III. Strategies, Tactics and Considerations for Settlement (cont'd)

E. Make sure to take the necessary time to negotiate, where possible, the terms of your Corporate Integrity Agreement (CIA).

- Failure to take the necessary time may will result in an overly onerous and expensive CIA.
- Most settlement agreements are accompanied by an OIG approved CIA. Where a company has a compliance program in place, the OIG will, on occasion, agree not to impose a CIA.

III. Strategies, Tactics and Considerations for Settlement (cont'd)

E. Make sure to take the necessary time to negotiate, where possible, the terms of your Corporate Integrity Agreement (CIA) (cont'd)

Key terms of the CIA that may be negotiable include:

- Auditing and monitoring process, including use of IRO
- Reporting obligations
- Length and scope of the exclusion provisions
- Length of the CIA
- Reminder: Purpose of CIA is to ensure that an entity undertakes monitoring and auditing of its compliance so as to avoid prohibited conduct in the future.