

Emerging Issues in Managed Care Litigation: An Examination of Recovery Actions and Rescission Litigation

Recovery Actions

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What Are “Recovery Actions”?

- Affirmative litigation against various types of entities seeking recovery of payments/overpayments made as a result of alleged misconduct in the health care marketplace.
- For purposes of this presentation, “affirmative recovery actions” do not include traditional subrogation efforts.

Why You Should Be Interested In Affirmative Recoveries – The Bottom Line

- Transforming Legal Departments from “Cost Centers” to “Profit Centers.”
 - Generation of “Income”
 - Off-Setting of “Losses”
- A sea change in what can – *and should* - be expected from legal departments.

From Cost Center To Profit Center – “Bringing Home The Bacon”:

- Traditional “recovery” efforts limited to subrogation claims attendant with monies paid to plan members for covered medical expenses don’t go far enough – particularly to redress alleged harm to payors and providers that is the direct result of misconduct in the health care marketplace.

Introduction

- This presentation will explore:
 - the emergence of affirmative recovery actions by payors and providers;
 - the legal theories and tactics involved; and
 - common defenses to and challenges with such actions.

The Beginnings: A \$1,000 toilet?

- The Government's Lead:
 - In the late 1980s and early 1990s, the Government pursued an aggressive campaign to fight fraud in the Defense Contracting Industry.



- Stories of \$1,000 toilets and \$500 hammers were widespread. The Government responded to public outcry for reform.

The Government's Response

- Using various statutory provisions and other legal “weapons” at its disposal, the Government undertook an aggressive enforcement campaign. Among others, the Government used:
 - **Criminal Prosecution;**
 - **Civil Fraud Enforcement;** and,
 - **Debarment and Suspension**



The Government's "Weapons" Against Defense Contractor Fraud:

- **Criminal Prosecution**
 - False Claims Act ("FCA")
 - Racketeer Influenced and Corrupt Organizations Act ("RICO")
 - Fraud (various types, incl. wire fraud)
 - Money Laundering
- **Civil Fraud Enforcement**
 - FCA
 - RICO
 - Fraud
- **Debarment and Suspension**



The Government's Success

- Hundreds of Criminal Convictions;
- Billions of Dollars in Fines, Penalties, and Civil Damages Awards;
- Hundreds of Contractors Suspended or Debarred;
- Hundreds of Corporate Integrity Agreements (“CIAs”);
- Restoration of Government Agency Program Integrity;
- Institution of Compliance Programs



Why Stop There? -- The Government Expands Enforcement To Health Care:

- With its appetite whetted through its successful campaign against Defense contractors, in the early to mid-1990s, it moved next to the health care industry.



Examples Of The Government's “Weapons” Against Medicaid/Medicare Fraud:

- **Criminal Prosecution**
 - FCA
 - Anti-Kickback Statute*
 - RICO
 - Fraud (various types, including wire fraud)
 - Money Laundering
- **Civil Fraud Enforcement**
 - FCA
 - Stark*
 - RICO
 - Fraud
- **Debarment and Suspension**

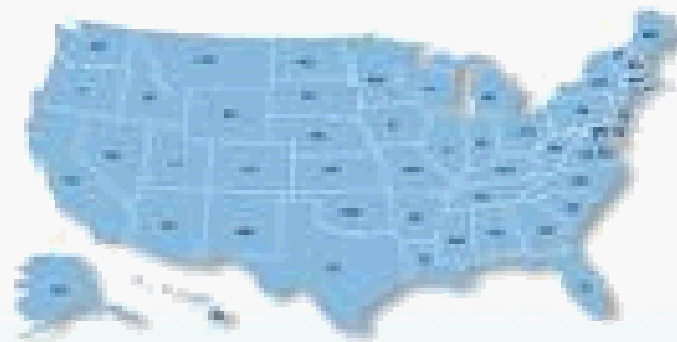
The Result (sound familiar?)

- Hundreds of Criminal Convictions;
- Billions of Dollars in Fines, Penalties, and Civil Damages Awards;
- Hundreds of Companies Suspended or Debarred from participation in federal (e.g., Medicaid/Medicare) programs;
- Hundreds of Corporate Integrity Agreements;
- Restoration of Government Agency Program Integrity;
- Emergence of Institution of Compliance Programs

... sound familiar?

The FTC and States Join In

- In addition to the enforcement efforts of the Department of Justice (“DoJ”), the Federal Trade Commission (“FTC”), and Attorneys General of the states and territories began to pursue their own.



The FTC's and AGs' Approach

- **The FTC**
 - Antitrust Enforcement
 - Antitrust Actions Seeking Injunctive Relief, Including Disgorgement
- **State AGs**
 - Antitrust Actions
 - False Claim Law Enforcement
 - Fraud and Abuse Enforcement

Examples Of The Types Of Conduct At Issue

- **Anticompetitive Conduct in the pharmaceutical and medical device industries and laboratory services:**
 - Monopolization/Attempted Monopolization (“reverse payment” agreements and otherwise)
 - Market Allocation
 - Price Fixing
- **Fraud and Abuse**
 - Upcoding
 - Unbundling
 - Charges for Services not performed
 - Off-Label Promotion
 - AWP/Marketing the Spread

An Epiphany – Private Payors And Providers Join In The “Fun”:



- Taking the Government’s lead, private payors began to wonder:

“Why not us?”

Legal Theories Linking Anticompetitive Conduct and Fraud and Abuse To Private Payor Damages:

- **Anticompetitive Conduct in the pharmaceutical, medical device, and laboratory services:**
 - Monopolization/Attempted Monopolization (through “reverse payment” agreements and otherwise)
 - Market Allocation
 - Price Fixing
- **Fraud and Abuse**
 - Upcoding
 - Unbundling
 - Charges for Services not performed
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What Legal “Weapons” Do Payors and Providers Have?

- Federal Antitrust Laws (for direct purchasers)
- State Antitrust Laws (for indirect purchasers)
- State False Claims Laws
- State Product Liability, Consumer Fraud, Unfair Business Practices Statutes
- State Fraud and Abuse Laws
- RICO
- Common Law (Unjust Enrichment)
- Medicaid/Medicare Provisions (e.g., 42 U.S.C. § 1395y(b)(3)(A))*

Historical and Emerging Defenses

- Standing
 - Antitrust/Illinois Brick
 - Hatch-Waxman Act/Other Federal Provisions
 - Self-Funded/ASO Issues
 - Subrogation Rights (Payor v. Patient)
- Rule 9(b) (for FCA/False Claims Law Cases)
- Rule 12(b)(6)
- **Pre-emption***
- Etc.

The Result?

- In just the past decade, affirmative recovery cases brought by payors and providers have returned billions of dollars to private payors and providers.



Some Representative Examples: A Few Cases And Varied Approaches

- ***Vioxx Marketing Fraud Litigation***, Case Code No. 619-TPP (Sup. Ct. N.J., Law Division, Atlantic County)
- ***Health Care Service Corp., et al. v. Mylan Laboratories, Inc., et al.***, Case No. 02-cv-01299 (TFH/JMF) (D.D.C.)
- ***In re: Plavix Direct Purchaser Antitrust Litigation***, Case No. 1:06-cv-00202 (MHW) (S.D. Ohio)
- ***In re: Plavix Indirect Purchaser Antitrust Litigation***, Case No. 1:06-cv-00226 (MHW) (S.D. Ohio)

Some Representative Examples (Cont.):

- ***In re: Oxycontin Antitrust Litigation***, Case No. 1:04-md-01603 (SHS) (S.D.N.Y.)
- ***In re: Bupirone Antitrust Litigation***, MDL No. 1413 (S.D.N.Y.)
- ***Oncology & Radiation Associates, P.A. v. Bristol Myers Squibb Co., et al.***, Case No. 1:01-cv-02313 (EGS) (D.D.C.)
- ***Blue Cross Blue Shield of Michigan, et al. v. Aventis S.A., et al.***, Case No. 2:01-cv-72806 (E.D. Mich.)

Some Representative Examples (Cont.):

- ***In re: Cardizem CD Antitrust Litigation***, MDL No. 1278 (E.D. Mich.)
- ***In re: Lorazepam & Clorazepate Antitrust Litigation***, MDL Docket No. 1290 (TFH); Misc. No. 99-ms-00276 (TFH) (D.D.C)
- ***Blue Cross of California, et al. v. SmithKline Beecham, et al.***, Case No. 97-cv-01795 (AVC) (D. Conn.)
- ***In re: Synthroid Marketing Litig.***, Case No. 1:97-cv- 06017 (EEB) (N.D. Ill.)

Approaches To Affirmative Recovery Actions

- Five Approaches:
 - **Do Nothing**
 - **“Business” Resolution**
 - **Monitor Ongoing/Class Litigation**
 - **File Suit**
 - **Participate In Ongoing/Class Litigation Using “Hybrid” Approach**

The “Do Nothing” Approach

- Payors and Providers may elect to do nothing
 - With nothing comes nothing
 - Potential millions of dollars in damages will be “left on the table” and never recovered
 - Lost opportunity to recover will also result in lost funds that could otherwise be used to be applied to operating costs
 - Program Integrity At Risk
 - Adverse Affect On Public/Member Relations

“Business Resolution”

- Some payors and providers, due to the desire to preserve strong relationships with the entities that have engaged in misconduct that has resulted in overpayments, may pursue a “business resolution” that does not involve litigation.
 - Discounted Future Purchases
 - Rebates
 - “Medicine Cabinet” Payments

Monitor Ongoing/Class Litigation

- This involves close monitoring of litigation brought by others, usually classes of direct and/or indirect purchasers. Payors and providers are unnamed class members and do not have any direct litigation/discovery obligations.
- If the litigation is successful, payors and providers can claim through the class settlement or recovery.
- If the litigation is unsuccessful, little is lost in terms of direct costs with opt-out possibility.

File Suit

- This approach speaks for itself and involves active litigation.
- Payors and providers who file suit maintain full control over the litigation.
- It involves the potential for great reward, but also the greatest risks in terms of costs (both internal and external) and, of course, the risk of no recovery.

Participate in Ongoing/Class Litigation – the “Hybrid” Approach

- Outside counsel file a notice of appearance (not suit) on your behalf in conjunction with ongoing/class litigation.
- As a represented member of a pre-existing class, you can actively participate in the litigation by working directly and collaboratively with class counsel.
- If the litigation is successful, you can elect to participate and claim through the class or opt-out and file suit on your own.

How To Assess The “Right” Approach: Some Considerations

- Amount of Damages
- Strength of Legal Claims/Defenses
- Likelihood of Success
- Costs of Recovery Pursuit/Litigation (expenses and internal costs)
- Ongoing Business Relationships
- Public Policy/Program Integrity
- Public Relations/Member Relations

Handout Materials

- DoJ Recovery Statistics (Overview and Health and Human Services)
- FCA Settlements 2000-2008 (Including Health Care Cases)
- “Fact Sheet: Department of Justice Efforts to Combat Health Care Fraud and Abuse”
- Recent Recovery Actions Related To Health Care Industry (By Segment)
- Representative Health Care/Affirmative Recovery Matters Handled By Current Crowell & Moring Attorneys