KING & SPALDING LLP

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Medicaid Fraud and Abuse Investigations, Prosecutions and Compliance Strategies

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Overview

- Why Is This Important?
- Current Areas of Interest
- DRA Amendments
- Compliance Strategies

Why Is This Important?

- Annual federal/state Medicaid spending: $300 billion
  - Federal share: $160 billion
- Medicaid spending lost to fraud:
  - Accurate figure: Unknown
  - Assuming 3% fraud rate: $5 billion (approximate)
- Types of fraud
  - Upcoding
  - Billing for services not provided*
  - Kickbacks*

Why Is This Important?

- Criminal convictions of individuals and companies
- Civil fines and penalties
- Administrative penalties
- Program exclusion (HHS OIG) and debarment
- Liability to third party payors

Medicaid Fraud Enforcement -- Shared Federal/State Responsibility

Federal Agencies

- Department of Justice
  - DOJ headquarters, US Attorneys
  - FBI
- HHS
  - HHS OIG
  - CMS

State Agencies

- State Medicaid agencies
- Medicaid Fraud Control Units (generally in AG's office)

Medicaid Fraud Control Units -- Spending and Accomplishments

Year	Federal Expenditures ($ millions)	Federal/State Recoveries ($ millions)	Convictions
2004	131	573	1,160
2003	120	268	1,096
2002	117	288	1,147
2001	96	253	1,002
2001	90	191	970

Current Areas of Interest

OFFICE OF INSPECTOR GENERAL

WORK PLAN

FISCAL YEAR 2006

Company	Settlement Date	Alleged Misconduct	Total Recovery	Medicaid Recovery
AstraZeneca	6/20/03	Marketing the Spread False Gov't Price Reporting	$ 355m	$ 24.9m
Bayer I	1/23/01	Marketing the Spread False Gov't Price Reporting	$ 14m	$ 14m
Bayer II	4/16/03	False Gov't Price Reporting	$ 257m	$ 242.1m
Dey	6/11/03	Marketing the Spread	$ 18.5m	$ 14.8m
GlaxoSmithKline I	4/16/03	False Gov't Price Reporting	$ 88m	$ 85.1m
GlaxoSmithKline II	9/20/05	False Gov't Price Reporting	$ 150m	$124m*
King	11/1/05	False Gov't Price Reporting	$ 124m	$117m*
Pfizer I	10/28/02	False Gov't Price Reporting	$ 49m	$ 49m
Pfizer II	5/13/04	Off-label Marketing	$ 430m	$ 152m
Schering-Plough I	5/3/04	Marketing the Spread	$ 27m	$ 27m
Schering-Plough II	7/29/04	False Gov't Price Reporting	$ 345.5m	$ 282.4m
Serono	10/17/05	Inducements	$ 704m	$ 305m
TAP Pharma	10/3/01	Marketing the Spread False Gov't Price Reporting	$ 875m	$ 56.7m
Total			$3.44b	$1.49b

* Estimate based on publicly available data

Deficit Reduction Act Amendments

United States Senate Committee On Finance

Hearings

Medicaid Waste, Fraud and Abuse: Threatening the Health Care Safety Net

June 29, 2005, at 10:00 a.m. in 216 Hart Senate Office Building

Member Statements:
Charles Grassley, IA
Max Baucus, MT

Witness Statements:

Panel I

Ms. Beatrice Manning, Qui Tam Relator

Mr. Timothy Coleman, Associate Deputy Attorney General, United States Department of Justice, Washington, DC

Mr. Robert Vito, Regional Inspector General for Evaluations and Inspections, Office of the Inspector General, United States Department of Health and Human Services, Philadelphia, PA

Mr. Patrick O'Connell, Assistant Attorney General, Office of the Attorney General, State of Texas, Austin, TX

Panel II

Mr. Daniel O'Brien, Senior Vice President, Erickson Retirement Communities, Baltimore, MD

Ms. Ruth Pundt, Resident, Erickson Retirement Communities, Parkville, MD

Ms. Julie Stone-Axelrad, Specialist in Social Legislation, Congressional Research Service, Washington, DC

Mr. Paul Pickerell, Manager, Financial Recoveries Division, Oregon Department of Human Services, Eugene, OR

Ms. Joyce Ruddock, Vice President, Long Term Care Division, MetLife Insurance on behalf of American Council of Life Insurers, Westport, CT

Dr. Judy Feder, Dean, Public Policy Institute, Georgetown University, Washington, DC

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Deficit Reduction Act Amendments

U.S. SENATE COMMITTEE ON

Finance

SENATOR CHUCK GRASSLEY, OF IOWA - CHAIRMAN

http://finance.senate.gov

Opening Statement of U.S. Senator Chuck Grassley of Iowa
Chairman, Senate Committee on Finance
Hearing, Medicaid Waste, Fraud and Abuse: Threatening the Health Care Safety Net
Wednesday, June 29, 2005

Thank you for joining us for day two of this important hearing. Yesterday we learned about some significant problems with the Medicaid program. At the conclusion of yesterday's hearing, we discussed efforts to correct them and to help reduce the impact that fraud, waste and abuse is having on the sustainability of this important program.

Today we will have two panels again to discuss more problems with fraud, waste and abuse in Medicaid. Our first panel is here to discuss prescription drug pricing, an issue that has been a central health care policy concern the past few years. Medicaid paid nearly $30 billion for prescription drugs in FY 2004 and the cost of both health care and drugs will continue to rise.

GAO Report: "CMS's Commitment to Helping States Safeguard Program Dollars is Limited" (June 2005)

- In FY 2005, CMS total staff resources allocated to Medicaid fraud/abuse control activities: 8.1 FTEs
- Annually, CMS conducts 7 to 8 on-site reviews of states fraud and abuse control activities -- for any given state, at best once every seven years.
- CMS has not developed a strategic plan for its efforts to curb fraud and abuse in the Medicaid program.
- GAO report was released at Senate Finance Committee hearing on Medicaid fraud/abuse -- and was major impetus behind DRA

Deficit Reduction Act Amendments

SEC. 6031. Encouraging Passage of State False Claims Acts

- If a State has in effect a law relating to false or fraudulent claims that meets the requirements of subsection (b), the Federal medical assistance
  percentage with respect to any amounts recovered under a State action
  brought under such law, shall be decreased by *10 percentage points*
- Subsection B requires the law to:
  - (1) incorporate the federal definition of a false claim
  - (2) include a qui tam reward at least as generous as that under federal law
  - (3) permit the state AG 60 days to review the allegation under

Deficit Reduction Act Amendments (cont'd)

SEC. 6032. Employee Education About False Claims Acts.

- Any entity that makes or receives more than $5,000,000 worth of payments to the State Medicaid plan must:
  - Establish a policy making employees/agents/contractors aware of the federal and state FCAs
  - Establish written policies detailing how the company polices fraud, waste and abuse
  - Include in an employee handbook a description of the relevant FCAs and a discussion of whistleblower protections

Deficit Reduction Act Amendments (cont'd)

SEC. 6034. Medicaid Integrity Program

- Establishes a Medicaid Integrity Program within CMS. The MIP is to review individuals, audit payment claims, identify overpayments, education providers
- The program director must develop a 5-year plan
- Appropriations have been made to hire 100 people for MIP
- Another appropriation of $25M to increase resources for OIG efforts
- Mandates Medi-Medi match data pilot program - matching Medicare and Medicaid data in attempt to identify meaningful discrepancies

Compliance Strategies

- Entities participating in Medicaid program should implement comprehensive compliance program based on guidelines by HHS OIG

- HHS OIG has issued Compliance Program Guidances for many industry sectors, including many involved in Medicaid program (*e.g.,* hospitals, DME suppliers, pharmaceutical manufacturers, etc.)

- One size does not fit all -- companies should tailor their CCPs to their activities, resources, organizational structure, and culture

- Take employee complaints seriously -- focus on federal and state FCAs means there will be more whistleblowers (usually current or

Fine Print

The views expressed in this presentation and during the accompanying discussion are those of the author and do not necessarily reflect the views of King & Spalding LLP or the firm's clients

The presentation and accompanying discussion are intended to provide a general overview of various regulatory issues and do not constitute legal advice

Biographical Summary

- John Bentivoglio is a Partner and Co-Chair of King & Spalding's FDA/Healthcare Group in Washington, DC. From 1997-2000, he served as Associate Deputy Attorney General and Special Counsel for Healthcare Fraud at the US Department of Justice. In these capacities, he advised the Attorney General and Deputy Attorney General on national enforcement initiatives, healthcare investigation and prosecution policies, interagency coordination, and related issues. From 1986-1992, Mr. Bentivoglio served as a professional staff member to Committee on the Judiciary, United States Senate, where he handled criminal law and procedure, white-collar crime issues (including healthcare and financial fraud), and international crime and terrorism legislation.
- In private practice, Mr. Bentivoglio represents a wide range of healthcare companies on a wide range of regulatory issues, including counseling companies on fraud and abuse issues under the Medicare/Medicaid Anti-Kickback Statute and related federal and state fraud/abuse laws; and pricing and reimbursement issues under federal and state healthcare programs. He also represents clients on internal investigations and compliance audits on healthcare compliance issues and in connection with investigations and enforcement actions by the US Department of Justice, HHS Office of Inspector General, and other federal and state enforcement agencies.