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Combating Medicaid Fraud & Abuse: Implications of the Medicaid Integrity Program October 24, 2006

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

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Current Areas of Interest

OFFICE OF INSPECTOR GENERAL WORK PLAN



FISCAL YEAR 2006

Medicaid Hospitals	. 21
Medicaid Graduate Medical Education Payments	.21
Hospital Outlier Payments	21
Medicaid Diagnosis-Related Group Payment Window	.21
Disproportionate Share Hospital Payments	.22
Hospital Eligibility for Disproportionate Share Hospital Payments	.22
Medicaid Long Term and Community Care	. 22
Payments to Public Nursing Facilities	.22
Community Residence Claims	.22
Assisted Living Facilities	.22
Medicaid Home Health Care Services to Dually Eligible Recipients	.22
Targeted Case Management	.23
Personal Care Services	.23
Home- and Community-Based Services Administrative Costs	.23
Additional Reimbursement for Distinct Part/Nursing Facilities of Public Hospitals	.23
Medicaid Eligibility and the Working Disabled	.23

Medicaid Mental Health Services	24
Medicaid Services for Mentally Disabled Persons	
Rehabilitation Services for Persons with Mental Illnesses	24
Community Mental Health Centers	24
Medicaid Supplemental Mental Health Payments to Prepaid Inpatient Health Plans	24
Nursing Home Residents with Mental Illness and Mental Retardation	24
Restraint and Seclusion in Children's Psychiatric Residential Treatment Facilities	24
Medicaid/State Children's Health Insurance Program	25
Duplicate Claims for Medicaid and State Children's Health Insurance Program	25
Detecting and Investigating Fraud and Abuse in State Children's Health	
Insurance Programs	25
Accuracy of State Children's Health Insurance Program Enrollment Data	25
State Children's Health Insurance Program Use of the National Correct Coding Initiative.	25

Medicaid Drug Reimbursement	26
Average Manufacturer Price and Average Wholesale Price	
Medicaid Drug Rebates-Computation of Average Manufacturer Price and Best Price	
Indexing the Generic Drug Rebate	
Drug Rebate Impact from Drugs Incorrectly Classified as Generic	
Overprescribing of OxyContin and Other Prescription Drugs	
Effect of Nominal Pricing on Medicaid Drug Rebates	
Medicaid Reimbursement of Drugs for Long Term Care Pharmacies	
Effect of Authorized Generic Drugs on Medicaid Drug Rebates	
Medicaid Payments for HIV Drugs	
Zero Dollar Unit Rebate Amounts	
Dispute Resolution in the Medicaid Prescription Drug Rebate Program	
Medicaid Generic Drug Utilization Among States	28
States Compliance With Federal Upper Limit Requirements	28
Medicaid Drug Pricing in State Maximum Allowable Cost Programs	
- + U	

Other Medicaid Services	28
Family Planning Services	
School-Based Health Services	
Adult Rehabilitative Services	
Outpatient Alcoholism Services	
Freestanding Inpatient Alcoholism Providers	
Medical Services for Undocumented Aliens	
Factors Affecting the Development, Referral, and Disposition of Medicaid Fraud Ca State Agency and Medicaid Fraud Control Unit Experiences	ses: 29

Medicaid Administration	30
Contingency Fee Payment Arrangements	
Upper Payment Limits	
Medicaid Provider Tax Issues	
State-Employed Physicians and other Practitioners	
Skilled Professional Medical Personnel	
Physician Assistant Reimbursement	
Medicaid Claims for Excluded Providers	
University-Contributed Indirect Costs	
Medicaid Accounts Receivable	
Section 1115 Demonstration Waiver	
Duplicate Payments for Medicaid Services	
Impact on the Medicaid Program of Certified Public Expenditures	32
Edits on Medicaid Payment	32
Administrative Costs for Medicaid Included in Temporary Assistance for	
Needy Families Grants	

Medicaid Asset Transfers and Estate Recovery Provision for Nursing Home Care	32
Medicaid Payments for County Administrative Services	
Medicaid Buy-In	32
Medicaid Eligibility in Multiple States	
Medicaid Administrative Costs	33
Medicaid Management Information Systems Costs	
Appropriateness of Medicaid Payments	
Medicaid Provider Enrollment Controls	
Medicaid Payment Safeguards	
Medicaid Pricing Comparisons	
Medicaid Fee-for-Service Payments for Beneficiaries Enrolled in Managed Care	
CMS Oversight of Home- and Community-Based Waivers	
Effect of State Medicaid Financing Arrangements on the Federal Share of	
Program Expenditures	
Medicaid and SCHIP Eligibility Determinations	

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Company	Settlement Date	Alleged	Total	Medicaid
	Date	Misconduct	Recovery	Recovery
AstraZeneca	6/20/03	Marketing the Spread	\$ 355m	\$ 24.9m
		False Gov't Price Reporting		
Bayer I	1/23/01	Marketing the Spread	\$ 14m	\$ 14m
-		False Gov't Price Reporting		
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	\$ 875m	\$ 56.7m
		False Gov't Price Reporting		
Total			\$3.44b	\$1.49b

* Estimate based on publicly available data

Deficit Reduction Act Amendments

United States Senate Committee On Finance



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

<u>Member Statements:</u> <u>Charles Grassley, IA</u> Max Baucus, MT

Witness Statements:

<u>Panel I</u>

Ms. Beatrice Manning, Qui Tam Relator

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

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

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

<u>Panel II</u>

<u>Mr. Daniel O'Brien</u>, Senior Vice President, Erickson Retirement Communities, Baltimore, MD

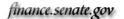
Ms. Ruth Pundt, Resident, Erickson Retirement Communities, Parkville, MD

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

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

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

<u>Dr. Judy Feder</u>, 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 amendments.

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 seal, and
 - (4) establish a civil penalty at least as punitive as the federal civil penalty

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
- Effective date of this provision is January 1, 2007.

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

General 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 former employees)

DRA-Specific Requirements

- Need to determine whether your organization makes or receives more than \$ 5 million under a state Medicaid plan
- Need to develop policies that provide "detailed information" as described in Section 6032.
 - Significantly, the Conference Report makes clear that Section 6032 "does not require the establishment of protocols and procedures for training of employees (i.e., only written policies are required)."
 - Entities may choose to provide training as a matter of prudence, but this is not required under the DRA.
- Interpretive and practical issues:
 - How detailed must the policies be?
 - What are entities required to do with respect to contractors and agents?
 - Can states go beyond the minimum requirements in Section 6032, are they likely to do so, and what should entities do to meet differing requirements?
 - Does the effective date (January 1, 2007) refer to when states must amend their plans or when covered entities come into compliance?

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.
- He received his undergraduate degree from the University of California, Berkeley, and his law degree from Georgetown University Law Center.