

**MANDATORY COMPLIANCE:
WHAT THE FUTURE LOOKS LIKE
HCCA SOUTH ATLANTIC
REGIONAL MEETING
1/28/11**

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GOALS OF THIS PRESENTATION

- HOW WE GOT HERE
- WHERE WE ARE
- MANDATORY COMPLIANCE REQUIREMENTS
- LESSONS FROM MANDATORY COMPLIANCE IN NEW YORK
- MY PREDICTIONS, NOT NECESSARILY MY POLICY PREFERENCES

HOW WE GOT HERE: THE PATH TO MANDATORY COMPLIANCE

- US Sentencing Guidelines-1990
- OIG/HHS Compliance Guidances-1999
- 1999 OIG Guidance re Excluded Persons
- Medicare Part C and D Mandatory Compliance Programs-2003
- Federal Acquisition Regulations-2008
- IRS-Revision of Non-Profit Return 990-2008

THE PATH TO MANDATORY COMPLIANCE

- New York Mandatory Compliance Program and Certification for Providers receiving >\$500,000 2009
- Medicare Part C and Part D Mandatory Compliance Programs-CMS Regulations 2009/Reviews-2010
- Affordable Care Act Section 6402-Report, Refund, and Explain Overpayments-3/23/2010; 6501-Terminated Persons-1/1/11
- Affordable Care Act Section 6401(a)(7)-Mandatory Compliance Plans for Skilled Nursing Facilities by March 23, 2012; others to follow
- OFCCP Directive-December 16, 2010 #293-coverage for Part C and D, Veterans' Affairs contractors and subcontractors

COMPLIANCE EXPECTATIONS- SENTENCING GUIDELINES

1. the organization exercises due diligence to prevent and detect inappropriate conduct by the Medicaid provider;
2. the organization promotes an organizational culture that encourages ethical conduct and is committed to compliance with the law; and
3. the compliance program is reasonably designed, implemented, and enforced so that the program is generally effective in preventing and detecting improper conduct.

Failure to prevent or detect specific offenses does not necessarily mean that the program is not generally effective in preventing and detecting such conduct.

Federal Sentencing Guidelines most recent amendment effective 11/1/2010 Section 8B2.1(a)

Medicare Part C and Part D Mandatory Compliance Programs- 2006

- Required by Prescription Drug Improvement and Modernization Act of 2003
- Required by regulation for Part D plans 42 CFR 423.504(b)(4)
- Required by CMS "Prescription Drug Benefit Manual" for Part D Plans, issued April 2006
- Required by contracts between CMS and Medicare Advantage, Part D plans
- Limited review of compliance programs through 2008
- OIG Report issued on CMS oversight

CMS "Prescription Drug Benefit Manual" for Part D Plans, issued April 2006

- CMS "Prescription Drug Benefit Manual" for Part D Plans, issued April 2006
- 17 requirements, 8 elements
- HHS/OIG Report (December 2006)
 - "CMS has not specifically audited PDF sponsors compliance plans or fraud, waste, and abuse programs to determine whether sponsors have addressed the eight elements established by regulation."

OIG REPORT: PRESCRIPTION DRUG PLAN SPONSORS' COMPLIANCE PLANS

- OEI-03-06-00100
- All PDP sponsors had compliance plans
- 72 of 79 sponsors did not address all 8 elements
- Two biggest failures
 - Designation of a compliance officer and compliance committee
 - Procedures for internal monitoring and auditing

2006- OIG REPORT: PRESCRIPTION DRUG PLAN SPONSORS' COMPLIANCE PLANS

- Plans did not address all CMS 17 recommendations
- Biggest weaknesses:
 - Fraud detection procedures
 - Fraud awareness training
 - Efforts to coordinate and cooperate with CMS and law enforcement on potential fraud

CMS FINAL CONTRACTING RULE- December 2007

- Contracting requirements for Medicare Advantage and Part D-including compliance
- Effective 1/1/2009
- Medicare Advantage Manual
- Final Rule backed off May, 2007 proposal for mandatory reporting of potential fraud or misconduct by plans

FEDERAL ACQUISITION REGULATIONS-MANDATORY DISCLOSURE, COMPLIANCE AND ETHICS PROGRAMS

- 48 C.F.R. §§ 9.406-2, 9.407-2 and 52.203-13- Mandatory Disclosure for Federal Contractors- also requires compliance and ethics programs for certain contractors, and reporting violations of criminal law and false claims.
- Does not cover Medicare A Hospitals Medicare B providers
- Medicare Advantage subcontractors, Part D plans, VA and Tricare plans?

OFCCP-HOSPITALS AS FEDERAL "SUBCONTRACTORS"

- OFCCP v. Florida Hospital of Orlando
- OFCCP argument-Humana contract with Tricare makes Florida Hospital a federal subcontractor
- OFCCP v. UPMC
- OFCCP argument-OPM contract with UPMC Health Plan for federal employees makes hospital a subcontractor
- Not Medicare or Medicaid provider agreements
- OFCCP Directive-December 16, 2010 #293
- Issue currently in litigation; implication for application of federal acquisition regulations?

IRS Form 990 Questions for Non-Profits on Governance Policies

Part VI Governance, Management, and Disclosure (Sections A, B, and C request information about policies not required by the Internal Revenue Code.)

Section A Governing Body and Management

Section B. Policies

	Yes	No
12a Does the organization have a written conflict of interest policy? If "No", go to line 13	Yes	
b Are officers, directors or trustees, and key employees required to disclose annually interests that could give rise to conflicts?	Yes	
c Does the organization regularly and consistently monitor and enforce compliance with the policy? If "Yes," describe in Schedule O how this is done	Yes	
13 Does the organization have a written whistleblower policy?	Yes	
14 Does the organization have a written document retention and destruction policy?	Yes	
15 Did the process for determining compensation of the following persons include a review and approval by independent persons, comparability data, and contemporaneous substantiation of the deliberation and decision		
a The organization's CEO, Executive Director, or top management official?	Yes	
b Other officers or key employees of the organization?	Yes	
Describe the process in Schedule O		

#1 THE MOST IMPORTANT MEDICAID INTEGRITY PROVISIONS OF PPACA

- MANDATORY REPORTING AND REPAYMENT OF OVERPAYMENTS BY "PERSONS"
- RETENTION OF OVERPAYMENT IS A FALSE CLAIM (invokes penalties and whistleblower provisions)

PPACA SECTION 6402 MEDICARE AND MEDICAID PROGRAM INTEGRITY PROVISIONS

- *"(d) REPORTING AND RETURNING OF OVERPAYMENTS.—*
- *"(1) IN GENERAL.—If a person has received an overpayment, the person shall—*
- *"(A) report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, at the correct address; and*
- *"(B) notify the Secretary, State, intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for the overpayment.*

SEC. 6402 (d) MEDICARE AND MEDICAID PROGRAM INTEGRITY PROVISIONS.

- *"(2) DEADLINE FOR REPORTING AND RETURNING OVERPAYMENTS.—An overpayment must be reported and returned under paragraph (1) by the later of—*
- *"(A) the date which is 60 days after the date on which the overpayment was identified; or*
- *"(B) the date any corresponding cost report is due, if applicable.*

PPACA SECTION 6402 (d) MEDICARE AND MEDICAID PROGRAM INTEGRITY PROVISIONS.

- *"(3) ENFORCEMENT—Any overpayment retained by a person after the deadline for reporting and returning the overpayment under paragraph (2) is an obligation (as defined in section 3729(b)(3) of title 31, United States Code) for purposes of section 3729 of such title. (False Claims Act)*

THE FLORIDA MEDICAID SELF-AUDIT PROCESS FOR DISCLOSURES

- **Florida Medicaid Bulletin Volume X Fall 2010**
- **“Medicaid provider self audits:** Providers who would like more information about conducting self-audits should contact the Agency’s Office of Inspector General, Bureau of Medicaid Program Integrity’s Self-Audit Coordinator, Pam Fante, at Pam.Fante@ahca.myflorida.com”
– 850 412 4600

COMPLIANCE/EXCLUSION

- ACA 6501-after 1/1/2011, if one state “terminates” provider, every other state must terminate that provider. If CMS revokes provider enrollment every state must also terminate their enrollment.
- Continues CMS emphasis on enrollment sanctions (differs from OIG exclusion)
- WHERE ARE THEY NOW? PROBLEM DOCTORS , NURSES, PHARMACISTS, THERAPISTS, AND PROVIDERS-STRAIGHTFORWARD FALSE CLAIM ACTION-CMS, OIG CITE 1999 STANDARD
- KEEPING BAD AND EXCLUDED PROVIDERS OUT OF HEALTH CARE- USING AUTOMATED BACKGROUND CHECKS, PRIOR LICENSE ACTIONS, PRIOR EXCLUSIONS-CMS Initiative in 9/23/2010 draft
- OMIG Webinar June 2010-available on OMIG Web site

GOVERNMENT TECHNIQUES TO ENCOURAGE COMPLIANCE

- Rewarding (sentencing guidelines)
- Modeling (OIG compliance guidance)
- Consulting with stakeholders (various OIG and OMIG advisory groups)
- Requiring performance outcomes (excluded persons)

GOVERNMENT TECHNIQUES TO ENCOURAGE COMPLIANCE

- Public reporting and disclosure (IRS 990)
- Condition of contract (CMS Part D)
- Certification requirement (OMIG)
- Mandated reporting of identified overpayments (OMIG, Affordable Care Act)
- Public disclosure of compliance failures (OMIG deceased patients project)
- Mandated compliance plans-structure and performance (CMS, OMIG)
- Measurement and audit of compliance programs (OMIG and CMS)

New York: Eight Elements of Compliance Program; Certification of Compliance

New York State Social Services Law Section 363-d.Subsection 2
Certification by December 31 of each year-“effective”

18 NYCRR Section 521.3 (c)

A compliance program shall include the following 8 elements:

- Element 1: Written Policies and Procedures
- Element 2: Designation of Compliance Officer
- Element 3: Training and Education
- Element 4: Communication lines to the Compliance Officer
- Element 5: Disciplinary Policies
- Element 6: Identification of Compliance Risk Areas and non-compliance
- Element 7: Responding to Compliance Issues
- Element 8: Policy of Non-Intimidation and Non-Retaliation

NEW YORK: MEASURING COMPLIANCE PROGRAMS

- Did they certify?
 - 50 percent by April 1; 80 percent by September 1
- Deceased patient billing
- Disclosures of overpayments-zero is a bad number
- Results of program, financial audits
- Data mining-excluded persons, outliers, behavior
- On-site reviews –review instrument, interviews with employees, board members

NEW YORK: MEASURING COMPLIANCE PROGRAMS

- Telephone calls
- “Please connect me with your compliance officer”
- “How do you check for excluded persons among employees and contractors?”
- “We have not received your certification; could you send me a copy?”
- “How often do you meet with the board or a board committee?”
- “Can we get a copy of your most recent IRS-990”

NEW YORK: MEASURING COMPLIANCE PROGRAMS

- Data Match Projects
 - Brown bagging of prescription drugs/drugs while inpatient
 - Duplicate payments from private insurers; no refunds to Medicaid or Medicare
 - Systems matches-inpatient receiving home health services
 - Transfer/discharge/readmission

NEW YORK: MEASURING COMPLIANCE PROGRAMS

- On-site compliance visits
- Eight elements
- Interviews
- Evidence of the program
- Web site
- Review instrument (on Web site)

AUDITING "EFFECTIVE" COMPLIANCE PROGRAMS

- Who is the compliance officer?
- To whom do they report?
- Do employees and vendors know about the compliance program?
- Who does billing? How accurate is it?
- Contingency fee contracting for coding and billing
- FMV reviews of physician payments
- Conflicts of interest
- Relationships with non-profits and the IRS form 990

BIGGEST COMPLIANCE FAILURE IN ESTABLISHED PROGRAMS

- Element 6: Identification of Compliance Risk Areas and non-compliance
- Element 7: Responding to Compliance Issues

THE FUTURE- Program Integrity and Data Mining Systems

- Data mining is a developing area – processing speed doubles every two years, software and analytic approaches move at same speed.
- Existing state data systems, at best, reflect reliable, tested systems and the state-of-the-art at the time of procurement. Existing New York systems procured five years ago, began operating three years ago.
- Significant opportunities for post-payment recoveries, and detection of compliance failures, including 6402 disclosure failures

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- Model compliance programs-hospitals, managed care (coming soon) and Compliance Alerts
- More than 3000 provider audit reports, detailing findings in specific industry
- Annual work plans
- New York excluded provider list
- Self-Disclosure protocol
- Corporate Integrity Agreements
- Subscribe to our free listserv
- Follow us on Twitter: NYSOMIG
- Link to sites for all 18 states which currently publish their state exclusion lists