DISSECTING THE TRENDS IN CORPORATE INTEGRITY AGREEMENTS:

Lessons to Learn
Leverage for Change
What is an IA/CIA?
Why is it a favored tool of HHS/DOJ?
Key enforcement laws
DOJ leadership priorities FY14
“Standard terms” evolved in 2013
Negotiate to avoid implementation issues
Recent cases / new concerns
www.oig.hhs.gov

What is a IA/CIA?

*a legal document that*

- outlines an entity’s commitment to certain actions to reach a civil settlement with HHS/DOJ
- in exchange
- entity will not be excluded from Federal health care programs
- goal
- integrity of claims - survival
Which healthcare entities are more likely to come under a CIA?

A. Public companies
B. Private companies
C. For profit hospitals
D. Pharma/DME
E. All the Above
All the above

No healthcare entity is immune!
Type by Industry FY09-FY11

Physician/Physician Provider Group 31%
Payor 2%
Pharma 11%
Ambulance 6%
Hospital 18%
Medical Device 8%
Other 24%

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Type of Entity FY09-FY11

Private Companies/Individuals 20%
Private Companies 43%
Public 23%
Individuals 14%
CIAs on the Rise

Why?
Will it continue?
“All fraud is waste ... 
All waste is not fraud”

HHS Inspector General

SNFs - $32B in 2012
25% claims in error in 2009
“Improper Payments” with 47% misreported MDS
$8 to $1
**Enforcement Works**

### Federal Enforcement Tools

- False Claims Act
  - Primary civil remedy (60%)
  - “reckless disregard” lowest level – so effective compliance program may shift claim from “false claim” to just an “overpayment”
  - 14 criminal convictions FY12
- Anti-Kickback / STARK
- False Statement
  - Don’t have to prove intent just the lie

### Quick Stats

- 647 qui tams in FY12
- 60+% in healthcare
- 70% increase in qui tams from FY08-FY12
- $7 recovery/$1 spent in enforcement effort
- $1.2M+ average settlement with individuals
- Relators’ bar better organized
- FY12 Relators’ rewards $439M
- FY12 recovered $4.9B
- 800+ criminal defendants

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DOJ Leadership Priorities

- End of 3Q13 DOJ had exceeded 650 new qui tams
- Recognize ‘finite resources’ so prioritize
  #1-health/safety issue in addition to loss $$$
  #2-$$$ at issue
  #3–egregious conduct – knowingly or just recklessly
  #4–”competent relator’s counsel serve as private AGs” – only intervene in 20%

  Health Care Fraud
  Financial Fraud
  Royalty Fraud
- Evaluate strengths/weaknesses of claims
- Higher duty than seeking $ - responsible to public
- Want pre-intervention exchange of discovery & financial impact info
- + for entity is reputational damage control esp. public companies
- “if litigate we are forced to extreme interpretation”
- “outside settlements we can tailor outside of statutory language
- “Damages” – “what government paid out”
  - **Total amount of claim regardless of quality of care received because no benefit went to gov’t only patient**
  - Recognize 8th Amendment arguments & recent decision in US v. Anchor Mortgage, 7th Circuit on damages
    - Treble damages & penalty within discretion of courts
    - Unsettled issues on constitutional authority for court to reduce excessive fines – DOJ position is court can lower to lowest permissible statutory damages
    - Deterrence is goal of penalty
George Houser, Sandy Springs, GA

- “Worthless Services” charge
- 2004 – 2007: Operated 3 nursing homes
- Received $32.9M from Medicare/Medicaid
- Conviction 1st in nation for that charge (bench trial)
- Sentence: 20 years & $6.7 restitution
### Common Structure of CIAs changing in FY13

**Pharma/Medical Device**
- IRO mandate in all
- 5 yr term
- 75% of CIAs were entered with individuals, private companies or a combo
- 2% required a Compliance Expert to advise the Board
- 71% arose from False Claims Act [FCA] case/investigation

**Hospitals/Physicians/LTC**
- **Before 2012 no IRO mandate** but now seeing ↑ in new layers of oversight/reporting
  - Physician Executive
  - Peer Review Consultant
  - Independent Cardiology Consultant
  - IRO [WakeMed]
- Independent/qualified monitors mandated for LTC
- 3 year terms
- 2/3 of individuals named in CIAs were physicians
- Physician whistleblowers common

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Standard Terms

1. **Standards and Procedures** – develop both “general” & “case specific” written standards & policies,
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Case: **WakeMed**  (Raleigh, NC)
- billing & reimbursement;
- documentation of medical records,
- proper order authentication,
- requirements for Care Management employees
Standard Terms

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2. **Oversight** - hire a CO/appoint a compliance committee; report not through legal, direct access to board with regular reporting
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**Case Study: WakeMed (Raleigh, NC)**

**Board Compliance Committee** must meet quarterly and *adopt a resolution – signed by each member* – summarizing its review of compliance requirements & the obligations of the CIA
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### Case Study: Allegiance Health Michigan
- **Physician Executive(s)** 1-3 required
  - Will provide oversight of medical staff quality of care, including performance improvement, quality assessment, patient safety, utilization review, peer review, credentialing/privileging, medical staff training/discipline
  - Members of senior leadership
  - At least quarterly reports re: quality of care to Board
  - Must be equivalent of at least 1 FTE

- **Medical Director of Cardiac Catheterization Lab**
- **Quarterly report to Physician Executive & Compliance Committee**
- **Peer Review Consultant**
Medical Director of Cardiac Catheterization Lab

- Quarterly report to Physician Executive & Compliance Committee
- ensuring the Cardiac Cath Lab is properly equipped, staffed, and managed
- ensuring appropriate recordkeeping of cardiac cath procedures;
- ensuring cardiac cath procedures peer reviewed for quality/outcomes
- developing criteria for assessment of clinical appropriateness of procedures
- assessing procedural outcomes with appropriate risk adjustment
- tabulating results achieved by individual cardiac catheterization interventionalist and by the Cardiac Cath Lab as a whole
- comparing individual interventionalists and Cardiac Cath Lab results with national benchmark standards with appropriate risk adjustment
- reporting results to relevant registries for benchmarking purposes
- tracking volume of cardiac cath interventionalists by individual interventionalists and by Cardiac Cath Lab
- reviewing interventionalist competence to perform cardiac cath procedures through credentialing and privileging
- implementing appropriate corrective actions for individual interventionalists who substantially deviate from national benchmark standards or otherwise are found to provide substandard care;
- monitoring relevant industry practice guidelines for changes, updates, and improvements.
Standard Terms Evolving

1. **Standards and Procedures** – develop both “general” & “case specific” written standards & policies,

2. **Oversight** - hire a CO/appoint a compliance committee; report not through legal, direct access to board with regular reporting

3. **Education and Training** – training program, how often, live or on-line, who is trained – employees, vendors, contractors

Scott Ellender, DO & Budget Optical – 9/30/2013

“training requirements may be satisfied only by the completion of courses provided by the Centers for Medicare & Medicaid Services (CMS) Medicare Learning Network (MLN), Ellender’s Medicare contractor, or other training courses that are submitted to OIG, prior to registration for the training course, for review and approval”
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4. **Monitoring and Auditing** – retaining IROs to conduct annual reviews, restricting employment of ineligible persons; claims review requirements –

Example: 50 paid Medicare claims submitted from a specified 12-month period
Exclusion Checks

Ineligible Persons: Excluded Providers and Entities

Section G or H in the typical CIA:

More expansive compliance protocols and requirements than if not under a CIA:

Definition of “Ineligible Persons”: Shall include an individual or entity who:

- Is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal Procurement or non-procurement programs, or
- Has been convicted of a criminal offense that falls within scope of 42 U.S.C Section 1320a-7(a), but has not yet been excluded, debarred, suspended or otherwise declared ineligible.

Requires screening all prospective Covered Persons prior to engaging services and as part of hiring or contracting process to disclose whether they are Ineligible Persons

Requires policy of Covered Persons to disclose immediately any debarment, exclusion, suspension or other event that makes that person an Ineligible Person
Sample Exclusion Language in CIA

Screening Requirements:
Depending on severity of non compliance can be expansive

WakeMed CIA included:

- All owners, officers, directors, and employees of WakeMed
- B) all contractors, subcontractors, agents and other persons who provide patient care items or services or who perform billing or coding functions on behalf of WakeMed, excluding vendors whose sole connection with WakeMed is selling or otherwise providing medical supplies or equipment to WakeMed and who do not bill the Federal health care programs for such medical supplies or equipment, and
- C) all physicians and other non-physician practitioners who are members on WakeMed’s active medical staff
Sample Exclusion Language in CIA

Don’t forget to self disclose if find your firm billed CMS for reimbursement of/for excluded person or entity.

- Removal Requirements and Pending Charges/Proposed Exclusions:

- If actual notice that Covered Person has become Ineligible, then shall remove from responsibility for, or involvement with operations related to Federal health care programs… or position for which compensation or items furnished, ordered or prescribed are paid in whole or part, directly or indirectly… until such time as reinstated into participation in Federal health care programs.

- If actual notice that a Covered Person is charged with criminal offense that would result in exclusion or is proposed for exclusion during employment or contract term, take actions to ensure responsibility not adversely affect quality of care to anyone receiving or claims submitted to any Federal healthcare program.
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4. **Monitoring and Auditing** – retaining IROs to conduct annual reviews, restricting employment of ineligible persons; claims review requirements – example 50 paid Medicare claims submitted from a specified 12-month period

5. **Reporting and Investigating** – must establish confidential disclosure program, process for reporting overpayment/”reportable events” within 30 days, annual reports to OIG on status of implementation efforts
QUALITY of CARE CIAs

- 11 to date – publicly posted
  Access effectiveness, reliability & thoroughness of providers’:
  - Internal quality controls systems
  - Response to quality-of-care issues
  - Development/implementation of CAP & timeliness
  - Proactive steps to ensure that patient receives basic care & treatment
  - Review of peer review process

Hospital incident reporting does not catch most harm ---- OIG

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Common Terms in Quality of Care CIAs

- 5 year terms
- COs must be member of senior leadership & not subordinate to GC/CFO & make quarterly reports to Board
- Creation of a Quality Assurance Compliance Committee
- Creation of a Board-level Quality Assurance Monitoring Committee
- Most involve LTC/Hospice – Hospital case required appointment of medical directors & peer review consultant
- Internal Audit Program for quality
- Training – 1 hr gen; 8 hr specific +8 hr quality training
- Special tracking of temp staff
- Staffing level concern reporting
- LOTS of special reporting to OIG/Monitor
- Monitor has immediate access
When FCA settlement resolves fraud that impacts patient care, OIG may enter "quality-of-care" CIA.

Quality CIAs require an independent quality monitor. Monitor will address specific issues underlying the allegations, AND look at entity's delivery of care and evaluate the provider's ability to prevent, detect, and respond to patient care problems.

Quality CIA does not equal a quality of care finding. No admission or substandard or worthless patient care.
Implementation Challenges Reported

Roundtable of Entities under CIAs

- 2/2012 Pharma
- All other entities
- [https://oig.hhs.gov/compliance/compliance-guidance/docs/Pharmaceutical-Compliance-Roundtable.pdf](https://oig.hhs.gov/compliance/compliance-guidance/docs/Pharmaceutical-Compliance-Roundtable.pdf)
- [https://oig.hhs.gov/compliance/complianceguidance/docs/Focus_on_Compliance.pdf](https://oig.hhs.gov/compliance/complianceguidance/docs/Focus_on_Compliance.pdf)

Common Implementation Issues

- Definitions of terms
  - “covered persons” and “relevant covered persons”
  - “substantial overpayment”
  - “error rate”
- Deadlines for initial implementation
- Training requirements
- Role of the CO, internal auditing and audit plans & role of the board
- Working with IROs
- Claims review requirements
- Arrangements review requirements
Common Mistakes in Negotiating a CIA

- Failing to educate DOJ/OIG attorneys on operational issues
- Failing to define vague terms – “error rate”…
  “substantial” overpayment –
- Failing to hire a subject matter expert to develop terms and requirements
- Delaying new/improved compliance program implementation while awaiting the CIA – start ASAP & be sure the CIA references the program
- Failing to view the IRO as ‘government’ representative
- Failing to adjust ‘attitude’ to circumstances when dealing with regulators
No ‘endorsed provider’ list
Entity will select but OIG/DOJ can approve or deny
Gov’t has access to the IRO’s work papers and correspondence and can question/perform a validation review of the work
Gov’t can demand replacement of an IRO
You may have multiple IROs for special areas [ex: coding firms, accounting, law, consulting] yet ‘best practice’ is to select a single firm to manage the entire IRO engagement
Experience in the subject matter area + experience with regulators critical so check, check, check references before you hire
Deferred Prosecution Agreement - DPA

- DPA involves criminal charges being brought & “deferred” for set term (usually 2 years); if company meets requirements then criminal charge will be dismissed
  - Keeps a hammer over the entity
  - Keeps government from potentially losing charges due to statute of limitations if it didn’t make the charges
- Increased use by DOJ – efficient means to hold corporation accountable & influence change in corporate compliance culture
- 1st use in a non-profit hospital was WakeMed (Dec 2012)
Leveraging CIAs to Protect & Educate Your Clients and Entities

- Sets forth components of “an effective compliance program”

- “Oversight” roles

- Quality/Compliance – importance of connecting

- Audit sampling – Error Rates “go bys”

- Budget Talks – how are you staffed, cost when program fails
Take Aways

- It can happen to any organization
- If self-discover & report, DOJ may waive CIA
- When you learn of issues – start remediation without delay
- Educate law enforcement re: operational challenges/concerns in implementation & negotiate terms
- Select IRO that is experienced
- Quality/Risk/Operations/Compliance – it’s a team sport
- Use CIAs as “Case Study” training tools & leverage– clear roadmap of regulatory expectations!
Thanks!

Alice Martin, Esq.
alice@martincompliance.com
256-710-8190

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