Morgan Lewis

Fraud and Abuse Update

2012 Health Law Institute
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Government Fraud and Abuse Enforcement Charging Full Steam Ahead

Affordable Care Act Regulatory Updates

- Proposed Rules Published on Sunshine Act and Reporting and Returning Overpayments
- Stark Self Disclosure Protocol's First Wave of Settlements Announced

Enforcement Targets

- Responsible Corporate Officials Risk Prosecution and Exclusion
- Kickback Recipients

Government Fraud and Abuse Enforcement Charging Full Steam Ahead

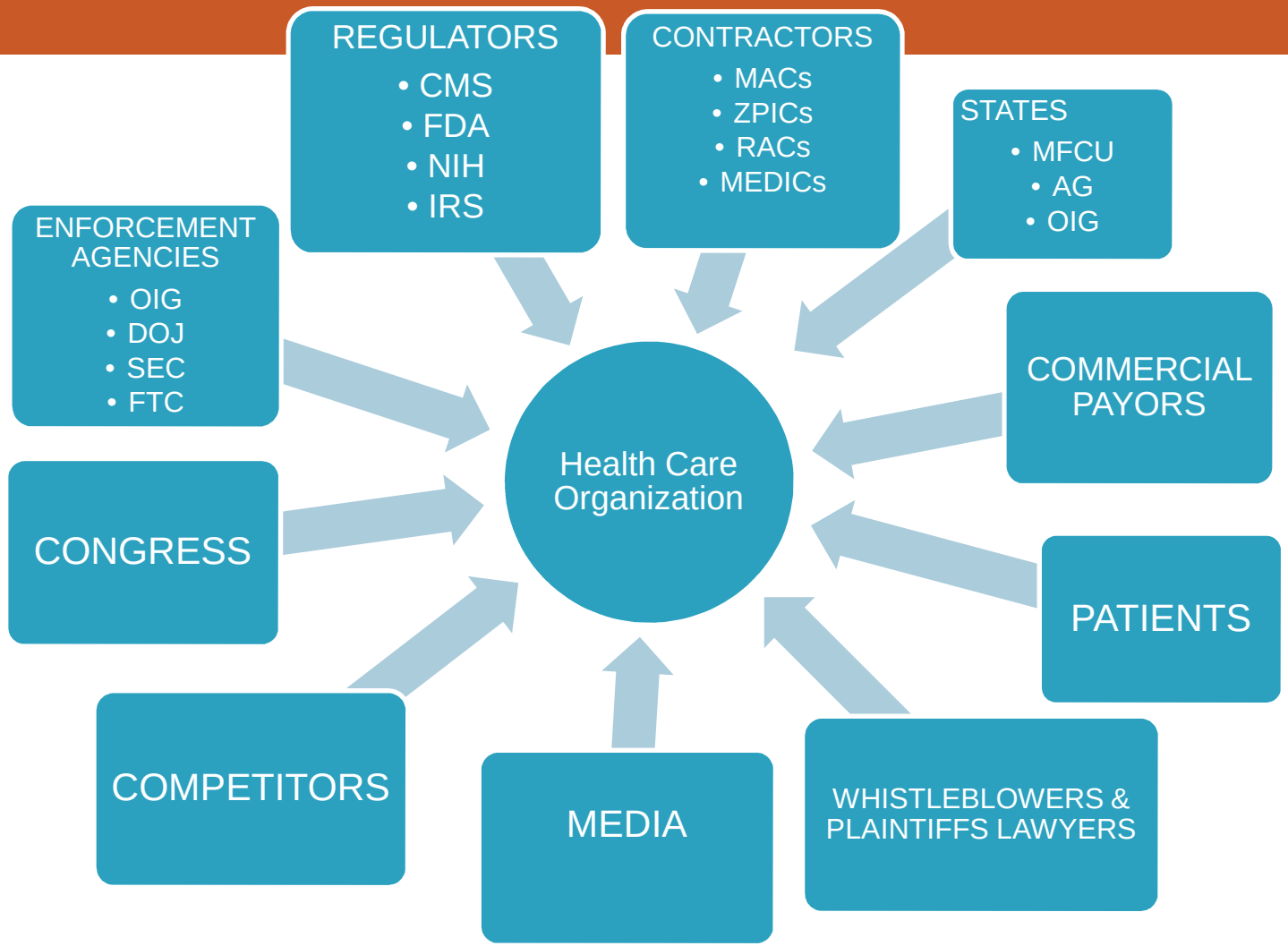
Investigative Tactics

- CMS and OIG Data Driven Detection
- Enhanced Suspension Authority Used in HEAT Crackdown

Industry Compliance

- OIG Hosts Trainings and Pharma Roundtable
- Strong Focus on Board and Management Accountability
- ACA Mandatory Compliance on the Horizon

Who's the Boss?



Health Care Fraud and Abuse Authorities "Every Breath You Take"

Criminal

- Criminal FCA, 18 U.S.C. § 287
- HIPAA/HITECH, 42 U.S.C. § 1320 d-6
- Fraud Offenses – Mail, Wire, and Health Care, 18 U.S.C. §§ 1341, 1343, 1347
- Federal Health Care – False Statements and Anti-Kickback, 42 U.S.C. §§ 1320a-7b(a)-(b)

Civil

- FCA, 31 U.S.C. §§ 3729–3733
- FDCA Prohibited Acts, 21 U.S.C. §§ 331-337
- Stark Law, 42 U.S.C. 1395nn

Administrative

- OIG CMP and Exclusion (Mandatory or Permissive), 42 U.S.C. §§ 1320a-7, 1320a-7a
- HIPAA and HITECH Act, 42 U.S.C. § 1320d-5
- EMTALA, 42 USC 1395dd et seq.

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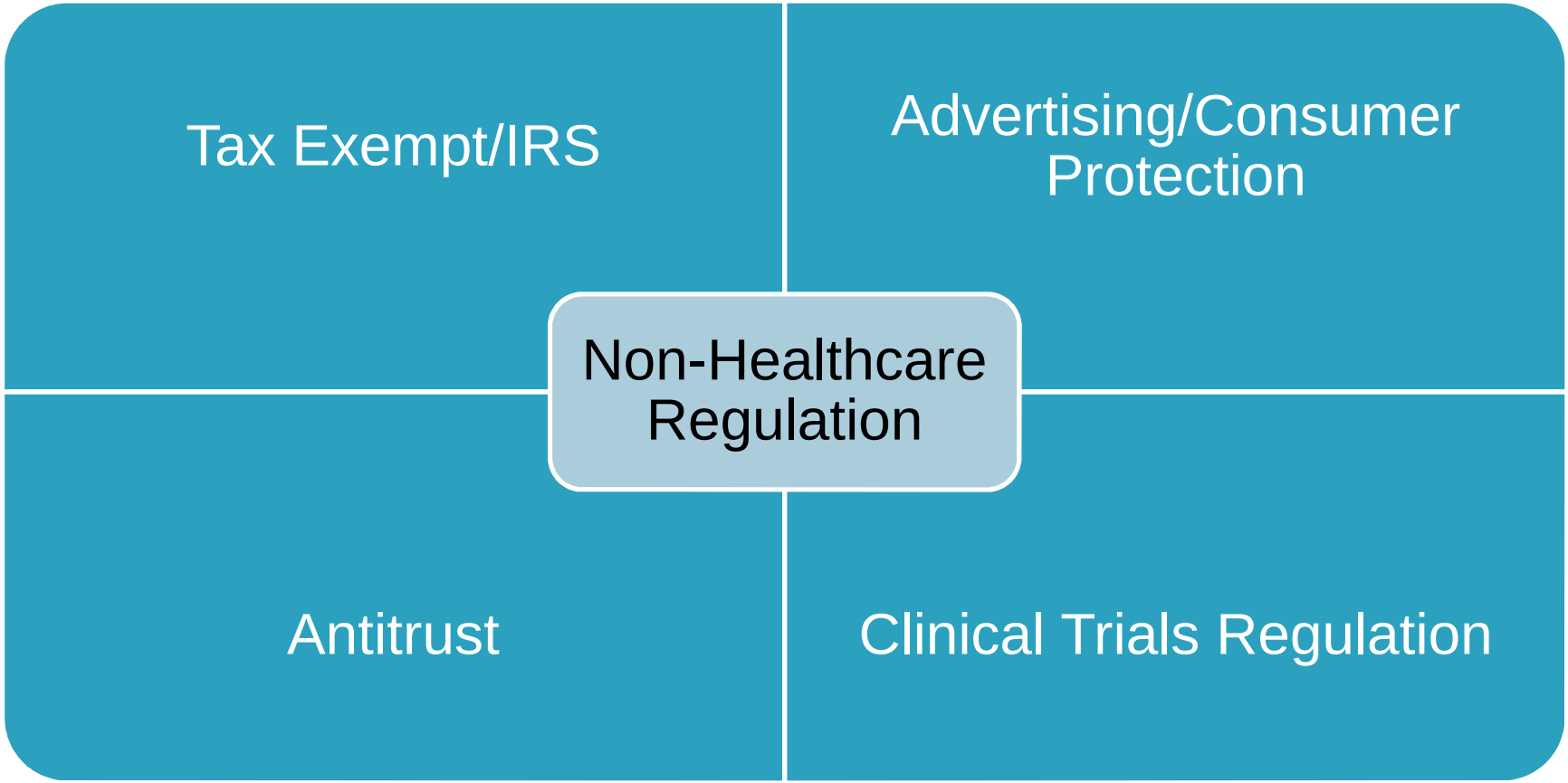

Health Care Fraud Enforcement Journey to the Modern Age

THEN	NOW
• Fraud and abuse enforcement efforts focused on **paid claims (aka "pay and chase")** • Agencies place premium on "**traditional fraud**," e.g., billing for services not rendered • Agencies in **silos** with fractured communication and missions	• Increased pre-payment scrutiny & **proactive fraud detection** • Significant recoveries based on **regulatory and billing violations**, e.g., coding • **Coordinated enforcement teams** and data sharing

Health Care Fraud Enforcement Journey to the Modern Age

THEN	NOW
• **Global settlements** resolved investigations in “one fell swoop”	• **Serial proceedings** where company settles then OIG bans executives, spinoff investigations of kickback recipients, and shareholder suits
• Health care **fraud sentences were less severe** than other crimes	• **Prison for regulatory infractions**, decades-long sentences for conspiracy convictions
• OIG to required **CIA as condition for exclusion waiver**	• OIG demands **divestiture of operating subsidiaries**, and **resignation of top officials** as conditions of settlement

Health Care Fraud Enforcement Journey to the Modern Age

THEN	NOW
• **No-Frills CIAs** with minimum standard terms applicable to any provider	• **Seven-Figure CIAs**, with Board obligations, management certifications, and legal department training
• **Media-shy** enforcement agencies that rarely publicized activities	• **Publicity savvy** agencies that host frequent press conferences, record podcasts, produce editorials, and develop flashy websites to show off their stats

Health Care Fraud Enforcement Journey to the Modern Age

THEN

- **Ad-hoc compliance efforts** with no industry standard

NOW

- Seven-element compliance programs are the norm, OIG guidance for 11 industries, **mandatory compliance** under ACA

Recent Cases/Investigations

Billion-Dollar Pharmaceutical Settlements for Marketing and More

- In November, GlaxoSmithKline announced $3 billion settlement with U.S. over sales marketing, Medicaid rebates, and **<u>development</u>** of diabetes drug
- GSK publicized voluntary compliance
  - *Sales targets eliminated, bonuses based on quality of service delivered*
  - *Commercial Practices Policies now conform to US PhRMA Code*

Recent Cases/Investigations

Billion-Dollar Pharmaceutical Settlements for Marketing and More

- In May, Abbott Labs paid $1.5 million and entered CIA to settle off-label allegations, and pled guilty to misbranding
- CIA includes board and management accountability provisions, **research compliance obligations**, and physician payment disclosure requirements

Recent Cases/Investigations

Managed Care Focus on Marketing and Fraud Reporting Violations

- Florida managed care plan paid $137.5 million to settle allegations of "**cherrypicking**", knowing retention of overpayments, and **sham special investigations** operations
- State of Florida fined Medicare HMO for **failure to promptly report Medicaid fraud** to state investigators

Recent Cases/Investigations

Crackdown on HIPAA Breaches

- $100,000 settlement with AZ physician practice for posting appointments on Internet-based calendar
- $1.5 million settlement with health plan for HITECH breach notification rule violation after hard drive theft compromised 1 million individuals' PHI

AFFORDABLE CARE ACT UPDATES

SUNSHINE ACT PROPOSED RULES

Collection to Begin in 2013

- Applicable manufacturers of drugs, devices, biological, or medical supplies reimbursable under Federal health care programs annual reporting of payments or transfers of value provided to physicians or teaching hospitals ("covered recipients")
- Applies to OTC drugs and devices requiring premarket approval
- Covered Recipients include GPOs and Physician-Owned Entities
- Transfer of value only covered if it exceeds $10 or $100 per year

AFFORDABLE CARE ACT UPDATES

PROPOSED RULE ON REPORTING AND RETURNING IDENTIFIED OVERPAYMENTS

- Clarifies definitions, causes a stir with 10-year lookback period
- 60-day deadline for claims related overpayments, cost report due date for amounts reconciled on cost reports
- “Identified” is “actual knowledge of the existence of the overpayment or…reckless disregard or deliberate ignorance of the overpayment
- Provider must make “reasonable inquiry” with “all deliberate speed” to identify overpayment
- Obligation to report and return suspended if provider enters OIG Self Disclosure Protocol
- Obligation to return overpayment suspended(but still required to report) if provider enters CMS Self Referral Disclosure Protocol

AFFORDABLE CARE ACT UPDATES

STARK SELF REFERRAL DISCLOSURE PROTOCOL

- CMS voluntary disclosure protocol for reporting Stark violations
- CMS has not issued deadlines on calculation of damages
- Protocol and settlements posted on CMS website https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self_Referral_Disclosure_Protocol.html
- March 2012 Report to Congress on implementation
- 150 disclosures submitted, 8 settlements to date, from $60 to $579K
- Most common disclosing parties are hospitals (125) and clinical laboratories (11)
- Most common violations relate to personal services exception, nonmonetary compensation exception, rental space exception, and physician recruitment arrangements exception

ENFORCEMENT TARGETS

RESPONSIBLE CORPORATE OFFICIALS

- Acting Associate Attorney General, Tony West: DOJ will “seek to disprove the ill-advised notion that health care fraud enforcement is simply the cost of doing business” “demanding accountability means we will consider prosecutions against individuals”
- Park Doctrine prosecutions increasingly common for FDC&A violations
  - corporate officials responsible for the actions of any person in the company
  - applies regardless of the size or complexity of the corporation itself
  - no proof of knowledge required to support conviction
- Exclusion can mean “corporate death penalty” for executives of pharma companies considered “too big to fire”

ENFORCEMENT TARGETS

FDA FACTORS TO CONSIDER IN MAKING PARK REFERRALS

- Whether the violation involves ***actual or potential harm to the public***;
- Whether the violation is ***obvious***;
- Whether the violation reflects a ***pattern of illegal*** behavior and/or ***failure to heed prior warnings***;
- Whether the violation is ***widespread***;
- Whether the violation is ***serious***;
- The quality of the ***legal and factual support*** for the proposed prosecution; and
- Whether the proposed prosecution is a prudent use of ***agency resources***.

ENFORCEMENT TARGETS

OIG (B)(15) EXCLUSION GUIDANCE

- Circumstances of Misconduct and Seriousness of Offense
- Individual's Role in Sanctioned Entity
- Individual's Actions in Response to Misconduct
- Information about Entity

ENFORCEMENT TARGETS

KICKBACK RECIPIENTS

- Recent kickback case charged a physician with accepting illegal kickbacks, and 8 other health care professionals with conspiracy
- Lew Morris warns to expect increased focus on kickback recipients
  - “We've successfully prosecuted physicians who've taken kickbacks, and we're able to tell them we can hit them with a $50,000 penalty, plus treble damages, plus exclusion,” he said. “It gives us great leverage to get them to sign CIAs.”

INVESTIGATIVE TACTICS

DATA AND TECHNOLOGY TAKES CENTER STAGE

- OIG Senate testimony touts data warehouse of Medicare Part A, B, and D claims data
  - Information used to identify fraudulent claims, billings for deceased providers, and use of compromised beneficiary numbers
- OIG credited data analytics with aiding in recent $452 million HEAT takedown
- CMS purchased $77M predictive modeling system to “increase scrutiny of claims before they’ve been paid”
  - Congress disappointed with results citing measly $7,591 in prevented payments

INDUSTRY COMPLIANCE

OIG TAKES TO THE STREETS

- OIG attorneys offered provider compliance training in Houston, Tampa, Kansas City, Baton Rouge, Denver, and Washington, D.C.
  - 16 video modules now available online at http://oig.hhs.gov/compliance/provider-compliance-training/index.asp
- Pharma roundtable with 42 compliance officers to discuss CIAs and post-CIA compliance
  - Providers to continue certifications, training and disclosure programs, and field monitoring

INDUSTRY COMPLIANCE

MANDATORY COMPLIANCE

- Section 6401 of ACA requires Medicare and Medicaid providers to establish compliance and ethics programs with “core elements”
- Awaiting word from HHS on definitions and guidance

TAKEAWAYS

- Regulators and enforcement agencies are scrutinizing “innocent mistakes” as closely as “traditional fraud”
- The government cares about individual accountability and so should you
- Early detection is critical—encourage internal reporting and enforce nonretaliation
- Compliance is an asset in the present aggressive enforcement environment

QUESTIONS?

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