HEALTH CARE COMPLIANCE ASSOCIATION
HEALTHCARE ENFORCEMENT COMPLIANCE CONFERENCE

LEGAL RISKS & VOLUNTARY SELF DISCLOSURE

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The Current Hostile Environment

- Criminal and civil enforcement risks
- Administrative and regulatory enforcement risks-Sanctions, Audits and Overpayments
- Whistleblowers
- Federal and state enforcement
- Media and public scrutiny
- Compliance program challenges and risks

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Legal and Organizational Risks

- Retaliation – Employees and Contractors
- Discovery in litigation
  - Audits
  - Compliance Investigations
  - Compliance Committee Records
  - Internal Investigations and Compliance Processes and Attorney-Client and Work Product

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Protecting Against Legal Risks

- Respond to all credible reports of non-compliant activity
- If you find a problem or weakness, fix it!
- Document compliance and remediation processes
- Get professionals involved as appropriate and necessary remedial action
- Establish privilege
- Don't ask questions if you are not prepared for the answers
- No substitute for the facts

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Obstruction of Justice

- Making a bad situation worse
  - Destroying or altering evidence-Litigation Hold Notice
    - Consider data collection issues – e-discovery
  - Proper advice to employees about government contacts
  - Care in conducting internal investigations and treatment of witnesses what to say/not say
  - Amateurs should not conduct internal investigations

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Anti-Kickback Statute and Stark Law

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False Claims Act

- 31 USC § 3719, the False Claims Act ("FCA" sets forth seven bases for liability. The most common ones are:
  1. Knowingly presenting, or causing to be presented, to the Government a false or fraudulent claim for payment
  2. Knowingly making, using, or causing to be made or used, a false record or statement material to get a false or fraudulent claim paid

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False Claims Act (cont'd.)

  3. Conspiring to commit a violation of the False Claims Act
  4. Knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly concealing or avoiding or decreasing an obligation to pay or transmit money or property to the government

- Obligation defined as an established duty, whether or not fixed, arising… from retention of any overpayment

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Elements of an FCA Offense

- The Defendant must:
  - Submit a claim (or cause a claim to be submitted)
  - To the "Government"
  - That is false or fraudulent
  - Knowing of its falsity
  - Seeking payment from the Federal treasury
  - Damages (maybe)

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Knowing & Knowingly

- No proof or specific intent to defraud is required
- The Government need only show person:
  - Had "actual knowledge of the information"; or
  - Person acted in "deliberate ignorance" of the truth or falsity of the information; or
  - Person acted in "reckless disregard" of the truth or falsity of the information

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Penalties

- Three times the amount of damages which the Government sustained
- Civil penalty from $5,500 to $11,500 per false claim (going up to $10,781.00 to $21,563.00)

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Qui Tam Actions & Government Intervention

- A private person ("Relator") may bring a False Claim Act action under the *qui tam* provisions of the FCA – The Whistleblower
- Government may intervene in a suit brought by Relator
- Relationship between Relator and Government
  - Collaborators in recovery of money
  - Rewards for whistleblowers

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FCA Statistics

- If the government intervenes and obtains recovery, the Relator can receive between 15% and 25% of the proceeds
- Since 1986, of all the *qui tam* actions filed, the average yearly intervention rate has been about 22-25%
- Billions in health care FCA recoveries since 1986, with annual average recoveries of $1.9 billion
- Recoveries have increased (higher penalties and more publicity)
- Whistleblower protection is provided to those that take lawful actions in furtherance of the *qui tam* suit, including initiation, investigation, testimony for, or assistance in the action

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Application of Fraud and Abuse Laws to Private Exchange Insurers

- Authority to implement any measure or procedure appropriate to eliminate fraud or abuse
- Federal payments to private insurance exchanges subject to False claims Act
- Federal payments to Medicare Advantage Plans?
- Wherever Federal money goes

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Administrative Sanctions

- Introduction

- The term "sanctions" represents the full range of administrative remedies and actions available to the Federal and State governments to deal with questionable, improper or abusive actions of health care providers under Federal Health Programs.
- Does not include private contractor actions, such as pre-payment and post-payment audit of claims and demands for overpayments and/or revocation of enrollment status

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Suspension, Offset And Recoupment Of Payments To Providers

- Suspension of payment is the withholding of payment by an intermediary or carrier from the provider of an already approved Medicare payment amount before a final determination is made as to the amount of any overpayment. See 42 U.S.C. § 1395y; 42 U.S.C. § 1396(b)(i)(2); 42 C.F.R. § 405.370(a).
- Offset is the recovery by the Medicare program of a non-Medicare debt (i.e. Medicaid) by reducing present or future Medicare payments and applying the amount withheld to the indebtedness. 42 C.F.R. § 405.370(a).
- Recoupment is the recovery by Medicare of any outstanding Medicare debt by reducing present or future Medicare payments and applying the amount withheld to the indebtedness. 42 C.F.R. § 405.370(a).

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Suspension, Offset and Recoupment of Payments to Providers (cont'd.)

- Administrative remedies for challenging suspension, offset or recoupment are limited
- Notice and opportunity to submit rebuttal statement
- If no rebuttal statement received, offset or recoupment automatically effective
- Applies until debt is liquidated or satisfied by other payment arrangements

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Suspension, Offset and Recoupment of Payments to Providers (cont'd.)

- Suspension of payments imposed by CMS through Medicare contractor
- Possession of reliable information of existence of overpayment or that payments to be made are incorrect, although additional information may be necessary for a conclusive determination
- Cases of suspected fraud, after consultation with OIG and/or DOJ, unless there is good cause not to suspend payment

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Suspension, Offset and Recoupment of Payments to Providers (cont'd.)

- Lasting a minimum of 180 days, but may be extended indefinitely by CMS, OIG and/or DOJ
- Suspension procedure set out at 42 C.F.R. § 405.372, 374, 375, et seq, including notice and opportunity for rebuttal and basis for extended period of suspension
- Suspension determination not appealable at 42 C.F.R. § 405.375(c)
- Section 6402(h)(2) of Affordable Care Act provides that Federal financial participation in Medicaid program shall not be made when state should have suspended Medicaid payments. See also, 42 C.F.R. § 455.2

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Exclusion
42 U.S.C. § 1320A-7

- When an exclusion is imposed, no payment is made to anyone for any item or service furnished, ordered, or prescribed by an excluded party under Medicare, Medicaid, or any other Federal Health Program. In addition, no payment is made to any business or facility – e.g., a hospital that submits bills for payment of items or services provided or ordered by an excluded party. See generally authority for exclusion at 42 C.F.R. Part 1001 et seq.

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Exclusion (cont'd.)

- Unless and until an individual or entity is re-instated, no payment will be made by Medicare, Medicaid, or any other Federal Health Program for any item or service furnished by an excluded individual or entity, or at the medical direction of, or on the prescription of, a physician or other authorized individual who is excluded.

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Exclusion (cont'd.)

- It is important to note that a provider may not submit claims to Medicare automatically upon the expiration of the period of exclusion. Excluded health care providers must petition for reinstatement, and be reinstated by the Department of Health and Human Services; Office of Inspector General ("OIG"), before they can lawfully submit claims to Federal Health Programs. An excluded individual or entity submitting, or causing the submission of, claims for items or services furnished during an exclusion period is subject to at least a civil monetary penalty, potential criminal liability, or both.

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Mandatory Exclusion

- The Secretary of Health and Human Services (the "Secretary") must exclude individuals and entities from Medicare, Medicaid, and other Federal Health Programs when they are convicted of certain offenses.
- First, if an individual or entity has been convicted of a criminal offense relating to the delivery of an item or service under Medicare or under any state health care program, (i.e. Medicaid) exclusion is mandatory.

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Mandatory Exclusion (cont'd.)

- Second, if an individual or entity has been convicted under federal or state law of a criminal offense relating to neglect or abuse of patients in connection with the delivery of a health care item or service, exclusion is mandatory. This is true even when such patients are not program beneficiaries.
- Third, exclusion is required for individual or entities that have been convicted, under federal or state law, of a criminal offense consisting of a felony relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct.

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Mandatory Exclusion (cont'd.)

- Finally, if an individual or entity has been convicted, under Federal or state law, of a criminal offense consisting of a felony relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance, exclusion must be imposed.

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Mandatory Exclusion (cont'd.)

- These exclusions may apply to those individuals or entities that (a) are or have been health care practitioners or providers, (b) hold or have held a direct or indirect ownership or control interest in a health care entity, (c) are or have been officers, directors, agents, or managing employees of the entity, or (d) are or have been employed in any capacity in the health care industry.

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Mandatory Exclusion (cont'd.)

- A mandatory exclusion based on an initial program-related crime must be imposed for at least five (5) years. Those convicted of three health care-related crimes must be permanently excluded from any Federal health care program. Individuals convicted of two health care-related crimes are subject to a mandatory minimum 10-year exclusion.

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Permissive Exclusion

- The Secretary may, but is not required to, exclude an individual or entity under numerous circumstances involving non-compliant activity
  - The length of a permissive exclusion ranges from one to three years and may be adjusted based on mitigating or aggravating factors as set forth in the governing regulations

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Corporate Integrity Agreements ("CIA's)

- The OIG imposes compliance obligations on health care providers as part of settlements of Federal enforcement actions arising under a variety of health care fraud statutes
- The option for a health care provider to agree to corporate integrity obligations is in return for the OIG's agreement to not seek program exclusion

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Corporate Integrity Agreements ("CIA's") (cont'd.)

- A part of global criminal and/or civil settlements
- May represent OIG's opinion on the effectiveness of the organization's compliance program and risk to Federal Health Programs
- CIA's adhere to the essential elements of an effective compliance program in the United States Sentencing Guidelines for Organizations

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Civil Money Penalty Law

- Civil Monetary Penalties Law
  - Since 1981, HHS has had the authority to levy administrative penalties and assessments against providers as punishment for filing false or improper claims or as a collateral consequence of prior bad acts. Social Security Act § § 1128 and 1128a. 42 U.S.C. § § 1320a-7 and 1320a-7a. Since then, the statute has been amended regularly to apply to other Federal programs and agencies and to apply to a broader range of acts and omissions.
  - Treble damages and penalties

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Civil Money Penalty Law

- The submission of false and fraudulent claims
- Illegal remuneration under the Stark and Anti-Kickback Statutes
- Other basis for Civil Money Penalties

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Legacy of Organizational Accountability Deemed Insufficient to Curtail Fraudulent and Abusive Practices

- Congressional and Executive Branch officials concerned that organizations are considering fines and penalties and Deferred Prosecution and Corporate Integrity Agreements as the cost of doing business and not deterring fraudulent and abusive conduct.
- Consequently recent enforcement actions target organization executives for criminal, civil and administrative liability based on organizational misconduct
  - Assumption is that organizational misconduct cannot occur without individual involvement
  - What individuals are responsible for organizational misconduct?
  - Responsible Corporate Officer Doctrine
  - Individual Accountability Policy ("Yates Memo")

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Responsible Corporate Officer Doctrine

- *U.S. v. Dotterweich and U.S. v. Park* (1975) originally established Responsible Corporate Officer Doctrine
- Corporate misconduct and violations of law can result in conviction of organization executives without individual involvement in wrongdoing or even knowledge that wrongdoing was taking place.
  - Recent application in cases involving violations of law which protects the health and safety of Medicare and Medicaid Program beneficiaries (i.e. Purdue Frederick, Inc. – promotion of "off-label" use of Oxycontin).

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Responsible Corporate Officer Doctrine (cont'd.)

- Individual criminal (i.e. plea to misdemeanor conviction), civil (i.e. individual multi million dollar fines) and administrative (Federal health program exclusion) liability for CEO, GC and CMO.
- Individual criminal, civil and administrative liability against Purdue executives not based on personal involvement or even knowledge of organization wrongdoing
- Based on Responsible Corporate Officer doctrine whereby each executive had "responsibility and authority to prevent or to promptly correct the organizational misconduct."

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Responsible Corporate Officer Doctrine and Program Exclusion

- Responsible Corporate Officer Doctrine – Strict liability application-without need for establishing personal involvement in wrongful conduct-criminal and administrative liability-misdemeanor and exclusion
- Pharma and Medical Device Industry for violations of Food, Drug & Cosmetics Act (Purdue Frederick and Synthes, Inc.)
- Exposure for health care organization and upper level management.
  - Responsibility for and authority to prevent or correct non-compliant activity.

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Broad Application And Additional Actions Against Individuals

- Corporate Integrity Agreements have already required individual responsibility and accountability for management officials, business unit managers and Chief Compliance Officers (i.e. Pfizer and Astra Zeneca)

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Broad Application And Additional Actions Against Individuals (cont'd.)

- Individual liability under the False Claims Act and Civil Money Penalty and Exclusion authorities
  - *U.S. v. Sulzbach* (i.e. General Counsel and Compliance Officer)
  - *OIG v. Montijo* (i.e. physician arrangements with medical device companies)
  - *OIG v. Baskt* (i.e. Stark law violations by CEO of Hospital)
- Recent actions against individuals
  - *U.S. v. Lauren Stevens* (i.e. criminal prosecution of General Counsel at Glaxo Smith-Kline)
  - *Denkel v. OIG* (i.e. exclusion of owner of diagnostic imaging company)

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What Does the Government Expect from Business Organizations

- Partnership with Federal and State governments in detecting and preventing misconduct and promoting an ethical corporate culture
- Organizations which fail to ferret out wrongful conduct and non-compliant activity will likely suffer the consequences of not doing so
- Cooperation in investigating an organization's own wrongdoing.

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"Cooperation" or "Unconditional Surrender"

- Cooperation taken into consideration in charging and sentencing decisions by Department of Justice
  - Organization's ability to make witnesses available
  - Disclosure of organization's internal investigation to identify facts and scope of conduct and responsible individuals
  - Disclosure in a timely and complete manner before facts become stale and to better enable recovery of losses by government

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"Cooperation" or "Unconditional Surrender" (cont'd.)

- Cooperation evaluated on case-by-case basis
- Deferred Prosecution Agreement – survival of business organization – Corporate Integrity Agreement with Department of Health and Human Services

- Circumstances exert acute pressure on business organizations to cooperate and compromise employee rights and protections and the Courts and United States Sentencing Commission have taken notice of impact on constitutional protections.

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Voluntary Disclosure Process

1. Investigation and Evaluation
2. Consider the Benefits and Risks
3. Consider Which Entity to Disclose to
4. Submit a Timely, Complete and Transparent Disclosure
5. Anticipate Government Validation
6. Resolution – Strategies and Options

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Is it "Voluntary?"

- Misprision of a Felony – 18 U.S.C. § 4 provides that "whosoever…having knowledge…of a felony…conceals and does not as soon as possible make known the same…shall be fined…imprisoned…or both
  - Requires active concealment
- Medicare Statute – 42 U.S.C. § 1320a-7b(a)(3) arguably makes it a felony to conceal or "fail to disclose" facts affecting right to receive payment

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Is it "Voluntary?"

- False Claims Act – Amendments to the FCA made as part of Fraud Enforcement and Recovery Act of 2009 (FERA) – 31 U.S.C. § 3729(a)(1)(G)
  - Illegal to "knowingly conceal…or knowingly and improperly avoid…or decrease…an obligation to pay or transmit money or property to the Government…
- Presentment of claim not essential for False Claims Act Liability under Affordable Care Act
- Affordable Care Act establishes "obligation" to report "identified" overpayment within sixty (60) days

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Disclosure Considerations

- Decision to disclose should be made in conjunction with counsel, but is a business decision – weighing potential risks and benefits
  - Where available, disclosure may offer protections too significant to pass up
  - Useful for substantial violations of law and whistleblower risk
  - Leaves as an open question more minor or isolated violations – time + expense + minimum settlement may make minor disclosures prohibitively costly
  - Continuing focus on compliance programs, good faith cooperation and prompt disclosure

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Weigh Pros and Cons With Counsel

- "Voluntary" vs. Essential Disclosures
- Potential advantages of disclosing:
  - Goodwill with government
  - Limiting possibility of external investigation
  - Expediting process of resolution
  - Reducing criminal and civil liability
  - Neutralizing whistleblower threat and lawsuits
  - Lessening overall damages and penalties

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Weighing Pros and Cons (cont'd.)

- Potential disadvantages of disclosing:
  - Financial loss – government motivated by recovery whether discovered or disclosed
  - Increased government scrutiny – validation process
  - No immunity from liability or prior commitments
  - Possible penalties for conduct that may have remained undiscovered.

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Choosing A Government Entity

- Self-disclosure can be made to:
  - Office of Inspector General of the Department of Health and Human Services (**OIG-HHS**) – Self Disclosure Protocol (SDP)
  - Centers for Medicare and Medicaid Services (**CMS**) – Self Referral Disclosure Protocol (SRDP)
  - Department of Justice, U.S. Attorney's Office (**DOJ**)
  - State Attorney General's Office

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General Guidelines

- Disclose billing errors and mistakes to entity processing claims and payment
- Disclose matters indicating civil liability under Civil False Claims Act to DOJ and/or OIG-HHS
- Disclose matters indicating criminal liability to DOJ and/or OIG-HHS
- Where, when and how to voluntarily disclose involves careful considerations

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OIG Self-Disclosure Protocol (SDP)

- Full cooperation and complete disclosure
- Submission violates laws, not a "mistake"
- Minimum settlement amount of $50,000
- Submit within 60 days from discovery
  - False Claims Act - 30 days limits damages
- Ongoing fraud scheme = more immediacy
- Physician self-referral matter with colorable anti-kickback statute violation
- Follow Self-Disclosure Protocol, done in 3 months

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CMS' Stark Self-Referral Disclosure Protocol (SRDP)

- Report and return overpayment 60 days from identification or from when cost report due
- Follow CMS' Protocol - SRDP
- Open access to all financial records, including work product
- Intended to resolve physician self-referral matters ("Stark" law) without extraordinary financial liability
- When no anti-kickback matter exists, use CMS' Protocol
- When anti-kickback matter exists, must choose either CMS or OIG for disclosure, not both

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Settlement Factors

- CMS may consider the following:
  - (1) the nature and extent of the improper or illegal practice;
  - (2) the timeliness of the self-disclosure;
  - (3) the cooperation in providing additional information related to the disclosure;
  - (4) the litigation risk associated with the matter disclosed; and
  - (5) the financial position of the disclosing party

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Self-Disclosure to DOJ

- DOJ is a law enforcement agency
- Unlike OIG and CMS, No formal protocol
- Criminal jurisdiction and civil authority under the False Claims Act
- Ability to release organization from liability

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Agency Coordination

- OIG confers with DOJ before acceptance
- OIG confers with DOJ before resolution
- OIG resolution not binding on DOJ
- Disclosing party can request DOJ or OIG presence in settlement discussions to resolve parallel liability
- CMS or Fiscal Agents can refer matters to OIG and DOJ

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Many Possible Settlement Factors

- Effectiveness of pre-existing compliance program
- Nature of the conduct and financial impact
- Ability to repay
- First-time offender, isolated and distinct incident
- Low-level bad actors
- Efforts to correct problem
- Successor liability under former management
- Period of conduct
- How matter was discovered
- Level of cooperation, candor, flexibility
- Relationships
- Etc.

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Final Advice

- There is no "one size fits all" approach to voluntary self-disclosure
- These decisions should be made with the assistance of competent and experienced counsel

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