



Compliance in the Post-Reform World

New and Expanded Fraud and Abuse Provisions

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New Environment

- Patient Protection and Affordable Care Act (“PPACA”)
 - PLUS
- Health Care and Education Reconciliation Act (“HCERA”)
 - PLUS
- Fraud Enforcement and Recovery Act (“FERA”)
 - Equals
- Many avenues of access into healthcare organizations

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New Environment

- PPACA as amended by HCERA contains 32 sections related to healthcare fraud and abuse and program integrity and makes significant amendments to existing criminal, civil and administrative anti-fraud statutes, most of which went into effect March 23, 2010
- FERA expanded definition of false claims to include retention of overpayments even if no false claim
 - If an organization or individual “knowingly conceals or knowingly and improperly avoids or decreases an **obligation** to pay or transmit money or property to the Government”, there can be liability under the FCA. (31 U.S.C. 3729(a)(1)(G))



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Fraud, Waste and Abuse Challenges

- Overpayments
 - Mandatory 60 day overpayment return obligation
 - Must report and return overpayment by the later of 60 days after the date overpayment was identified OR the date any corresponding cost report is due, if applicable.
 - Must notify the Secretary of HHS, State, FI or Carrier IN WRITING of the reason for the overpayment



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Fraud, Waste and Abuse Challenges

- Anti-Kickback Statute
 - Specific intent requirement relaxed
 - A violation of AKS now constitutes a false or fraudulent claim under FCA
 - Definition of remuneration is amended for the beneficiary inducement provisions to exclude any remuneration that promotes access to care and poses a low risk of harm to patients and federal healthcare programs



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Fraud, Waste and Abuse Challenges

- False Claims Act Qui Tam Public Disclosure Bar
 - FCA amended to provide that the public disclosure bar is not jurisdictional and does not require dismissal if the government opposes dismissal
 - State proceedings and private litigation are not qualifying public disclosures
 - Original source exception amended to eliminate direct knowledge requirement



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Fraud, Waste and Abuse Challenges

- Limitations on Stark Law Exceptions
 - Limits Whole Hospital and Rural Provider exceptions to hospitals that have Medicare provider agreements and physician ownership or investment as of 12/31/2010
 - Limitation on expansion of facility capacity
 - Retroactively imposes disclosure requirements on In-Office Ancillary Services exception



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Fraud, Waste and Abuse Challenges

- Stark Law Self-Disclosure Protocol
 - Voluntary Self Referral Disclosure Protocol created for violations of the Stark Law
 - Provides for agency discretion to resolve Stark violations and authorizes HHS to reduce the amount due and owing for all Stark violations, considering such factors as the nature and extent of the improper practice and timeliness of the disclosure
 - CMS released the SRDP on Sept. 23, 2010



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Fraud, Waste and Abuse Challenges

- Health Benefits Exchanges
 - Payments made in connection with the new Health Benefits Exchanges will fall within the scope of the FCA, to the extent that such payments include any federal funds



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Fraud, Waste and Abuse Challenges

- Expanded RAC Activities
 - PPACA expands RAC audits of providers to
 - Medicare Parts C and D
 - Medicaid



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Fraud, Waste and Abuse Challenges

- Healthcare Fraud Criminal Statute
 - Intent requirement amended- now provides that proof of actual knowledge of the healthcare fraud statute or specific intent to violate the statute is not required
 - Definition of healthcare offense amended to include violations of the AKS, among other things



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Fraud, Waste and Abuse Challenges

- US Sentencing Guidelines amended
 - Guidelines amended with respect to individuals convicted of healthcare fraud offenses related to any federal healthcare program
 - Offense level increased anywhere from 20% to 50% where the loss involves more than \$1 million



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New Resources

- Gov't has new resources
 - Expanded HHS subpoena power
 - Additional funding- over \$300 million over the next 10 years
 - Expanded use of RACs
 - Agency data sharing



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Administrative Penalties

- Expansion of Administrative Penalties
 - Authorizes HHS to suspend Medicare and Medicaid payments to a provider "pending an investigation of a credible allegation of fraud"



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Administrative Penalties

- Exclusion
 - HHS authority to exclude any entity that knowingly makes or causes to be made a false statement or omission in an application, agreement, bid or contract to participate as a provider under a federal health care program
 - Requires that state Medicaid agencies exclude any entity that owns, controls, or manages an entity that has unpaid, delinquent overpayments; is suspended, excluded, or terminated from Medicaid; or is **affiliated** with an individual or entity that has been suspended, excluded or terminated from Medicaid



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Administrative Penalties

- Civil Monetary Penalties
 - New grounds for imposing CMPs, including:
 - the knowing retention of an overpayment
 - knowingly making or causing to be made a false statement in an application to participate as a provider



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Accountable Care

- PPACA makes changes to the health care payment and delivery system
 - Implications for Accountable Care Organizations



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ACO- Legal Considerations

- **Stark Law** – Not likely to apply if incentives are structured appropriately
- **Anti-Kickback Statute** – Underscores need for fair market value analysis of available incentives
- **CMP** – Ensure incentives award quality of care, not reduction in necessary services
- **Tax** – Requires consideration of the powers reserved to the tax-exempt organizations involved
- **State** – Necessitates analysis of state fee-splitting, self-referral and kickback statutes



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Tax Exemption

- AKS Safe Harbor for EMR donations
 - Non-profit hospitals can give e-health records software and support services to staff doctors without jeopardizing their tax-exempt status



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Thank you.



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