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| <p>1. Compliance Program</p> | <p>Following rules and regulations</p> |
| <p>2. Integrity Program</p> | <p>Values doing the right thing</p> |

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| <p>3. Current Compliance activities in many organizations</p> | <ul style="list-style-type: none">• Equal Employment Opportunity Commission (EEOC)• Employee Retirement Income Security Act (ERISA)• Wage and Hour Rule• Occupational Safety and health Administration (OSHA)• Nuclear Regulatory Commission• Joint Commission on Accreditation of Healthcare Organization (JCAHO)• Research compliance |
| <p>4. What is a Compliance Program?</p> | <ul style="list-style-type: none">• Prevention, Detection, Collaboration, and Enforcement• System of policies and procedures developed to assure compliance with and conformity to all applicable federal and state laws governing organization• Ongoing process, part of fabric of organization, commitment to ethical way of conducting business |

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| <p>5. Who needs compliance? Why?</p> | <ul style="list-style-type: none">• Physicians practices• Medicare• Ambulance Services• 3rd Party Billing• Pharmaceutical Manufacturing• Hospitals• Laboratories• DME• Home Health <p>Memory aid: APRN & 3 MD work In HHHC</p> |
| <p>6. HHS Office of Inspector General (OIG) in conjunction with Justice Department is responsible for enforcing the rules and regulations under</p> | <p>HHS Office of Inspector General (OIG) in conjunction with Justice Department is responsible for enforcing the rules and regulations under Medicare/Medicaid laws outlined as part of the Social Security Act and administered by CMS</p> |

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| <p>7. Government estimates on fraud</p> | <p>10% of total US health care expenditures, about \$100 billion annually.</p> |
| <p>8. Justice Department</p> | <ul style="list-style-type: none">• Violent Crime - 1st Priority• Health care fraud - 2nd Priority |

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| <h2>9. Benefits of Compliance Program</h2> | <ul style="list-style-type: none">• Safeguards organization legal responsibility to abide by applicable laws and regulations• Demonstrate to employee and community the organization's commitment to good corporate conduct• Identify and prevent criminal and unethical conduct• Improve the quality of patient care• Create a centralized source of info. on health care regulations• Develop a methodology that encourages employees to report potential problems• Develop procedures that allow the prompt, thorough investigation of alleged misconduct• Initiate immediate and appropriate corrective action• Reduce the organization remedies, such as program exclusion |
| <h2>10. Why Compliance Programs are Essential</h2> | <ul style="list-style-type: none">• Payback to fiscal intermediaries or carriers may result in audited services• Probation and court imposed programs• Government designed programs• Exclusion from government program• Reduced threat of qui tam (whistle-blower) lawsuit |

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| <p style="text-align: center;">11. OIG Top 10 Reasons to Implement a Compliance Program (1 -5)</p> | <ul style="list-style-type: none">• Adopting a compliance program concretely demonstrates to the community at large that a provider has a strong commitment to honesty and responsible corporate citizenship.• Compliance programs reinforces employee' innate sense of right and wrong.• An effective compliance program helps a provider fulfill its legal duty to government and private payors.• Compliance programs are cost effective.• A compliance program provides a more accurate view of employee and contractor behavior relating to fraud and abuse. |
| <p style="text-align: center;">12. OIG Top 10 Reasons to Implement a Compliance Program (6-10)</p> | <ul style="list-style-type: none">• The quality of care provided to patients is enhanced by an effective compliance program.• A compliance program provides procedures to promptly correct misconduct.• An effective compliance program may mitigate any sanction imposed by the government.• Voluntarily implementing a compliance program is preferable to waiting for the OIG to impose a Corporate Integrity Agreement (CIA).• Effective corporate compliance programs may protect corporate directors from personal liability. |

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| <p>13. Corporate Integrity Agreement(CIA)</p> | <p>If provider does not have one in place, the OIG will develop one that is enforceable through corporate integrity agreement. CIA has detailed policy, training, audit, and reporting requirements that are typically in force for 5 years and involve substantial oversight.</p> |
| <p>14. HIPAA of 1996</p> | <p>Makes it a criminal offense to submit claims based on incorrect codes or medically unnecessary services and the government has the power to exclude the organization from Medicare, Medicaid, and a long list of other government programs.</p> |

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| <p>15. Balance Budget Act of 1997</p> | <p>Has three strike rule - 3 strikes and you're out clause, requiring permanent expulsion for healthcare organization found guilty of fraud a third time.</p> |
| <p>16. False Claim Act (FCA)</p> | <ul style="list-style-type: none">• Empowers government to investigate and bring civil action in fraud case. Implemented during Civil War to curb war time price gouging• Also allow private citizen to bring civil actions against an organization in the name of United States. This action provided significant incentive for the private citizen to come forward. This action is better known as Qui Tam, whistle blower.• Sometimes called Lincoln's Law as it implemented during the Civil War to protect against price gouging to the military. |

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| <p>17. CIA - (Corporate Integrity Agreement)</p> | <p>Organization does not admit fault or liability but does submit itself to government corrective action plan. Government imposed CIA have been onerous in the past and is expected to become more onerous in the future. CIAs are usually 3-5 years but can last as long as 8 years.</p> |
| <p>18. February 27, 1997</p> | <p>Date of OIG open letter to all providers - encourages health care organization to implement compliance programs in order to protect themselves from fraud and abuse. With that letter, Model compliance plan for Clinical Laboratory was offered as guidance. Since that time, Model compliance plan has been implemented in many areas.</p> |

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| <p>19. 1984 Sentencing Reform Act</p> | <p>Designed to correct inequities in deferral sentences. Includes the Federal Sentencing Guidelines that include guidance for assessing fines and detailed method for calculation of a "culpability score."</p> |
| <p>20. 2004 - Federal Sentencing Commission released "Ch 8 Part B - Remediating Harm from Criminal Conduct, and Effective Compliance and Ethics Program"</p> | <p>These revisions focused on effective compliance and ethics programs.</p> |

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| <p>21. 4 Aggravating Factors to a culpability score</p> | <ul style="list-style-type: none">• If an upper level employee has "participated in, condoned, or was willfully ignorant of the offense"• If the violation is a repeat offense• If the government was hindered during its investigation and• If awareness of and tolerance of the violation were pervasive |
| <p>22. 4 Mitigating Factors to a culpability score</p> | <ul style="list-style-type: none">• If the organization had an effective compliance program, even though there was a violation• If the organization reported the violation promptly• If the organization cooperated with the government investigators• If the organization accepted responsibility for the violation |

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| <p>23. Federal Sentencing Commission has stated</p> | <p>"Compliance and ethics programs shall be designed, implemented, and enforced so that the program is generally effective in preventing and detecting criminal conduct. The failure to prevent or detect the instant offense does not necessarily mean that the program is not generally effective in preventing and detecting criminal conduct."</p> |
| <p>24. 7 Elements in OIG CPG Guidance for Hospital</p> | <ul style="list-style-type: none">• Written standards of conduct• Designating a chief compliance officer and other appropriate bodies• Effective education and training• Audit and evaluation techniques to monitor compliance• Reporting process and procedures for complaints• Appropriate disciplinary mechanism• Investigation and remediation of systemic problem |

25. Obstacles to Effective Compliance Implementation (1-5)

- Commitment and buy-in
- Lack of funding
- Too many roles for compliance professional
- Interpreting laws and regulations
- Lack of resources and staff

26. Obstacles to Effective Compliance Implementation (6-10)

- Lack of education and training
- Resistance to change
- Lack of or poor communication
- Fear of retaliation/retribution
- No internal enforcement

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| <p>27. In all OIG program guidance</p> | <p>The first prescribe elements calls for the development and distribution of written standards of conduct, as well as written policies and procedures that promote a commitment to compliance."</p> |
| <p>28. Code of Conduct: Content Checklist</p> | <ul style="list-style-type: none">• Demonstrate system wide emphasis on compliance with all applicable law and regulations• Written plainly and concisely so all employees can understand the standards• Includes internal and external regulations• Mentions organizational policies without completely restating them• Is consistent with company policies and procedures |

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| <p>29. Code of Conduct and Employees</p> | <ul style="list-style-type: none">• All employees must receive, read, and understand the standards• A supervisor should explain the standards and answer any questions• Employee should attest in writing that they have received, read, and understood the standards• Employee compliance with standards must be enforced through appropriate discipline when necessary• Discipline for non-compliance should be stated in the standards |
| <p>30. Code of Conduct Purpose</p> | <ul style="list-style-type: none">• To present specific guidelines for employees to follow• To confirm that all employees comprehend what is required of them• To provide a process for proper decision making• To confirm that employees put standards into everyday practice• To elevate corporate performance in basic business relationship• To confirm that the organization upholds and supports proper compliance conduct |

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| <p>31. Compliance policies and procedures should be integrated into existing policies</p> | <p>Only thing worse than not having a policy is having a policy and not following it. Develop policy carefully and review them regularly. Make sure they are realistic and measurable.</p> |
| <p>32. Development of policies and procedures begin with areas of risk.</p> | <p>Targeting areas on OIG Work Plan that apply to your organization and adequately address them in your policies and procedures.</p> |

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| <p>33. Every organization needs policies and procedures for:</p> | <ul style="list-style-type: none">• Internal assessment• Record Retention (where, how long)• Self-disclosure• Medicare sanction checks (LEIE)• Billing policies• Unbundling• Credit Balance• No charge visit• Incomplete/Unsuccessful procedure• Documentation requirement |
| <p>34. Upcoding</p> | <p>Using a billing code that provides a higher reimbursement rate than the billing code that actually reflects the service furnished. Major focus of OIG enforcement efforts and HIPAA added additional civil monetary penalty to OIG sanctions.</p> |

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| <p>35. DRG Creep</p> | <p>Using a DRG code that provide a higher payment rate than the DRG code that accurately reflects the service furnished to the patient.</p> |
| <p>36. Teaching physician Rule</p> | <p>Special documentation requirement for services provided by residents and teaching physician.</p> |

37. Project Bad Bundled

OIG Effort to identify laboratory tests processed in groups but reported individually at a higher rate of reimbursement also unbundling.

38. Lincoln's Law

Refers to the False Claims Act given that the FCA was introduced during the Civil War.

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| <p>39. 72 hour rule</p> | <p>Stipulates that diagnostic tests provided on an outpatient basis within 72 hours of an admission must be billed as part of the admission DRG</p> |
| <p>40. Anti-kickback statute</p> | <p>Prohibits any knowing and willful conduct involving solicitation, receipt, offer, or payment of any kind of remuneration in return for referring an individual or for recommending or arranging the purchase, lease, or ordering of an item or services that may be wholly or partially paid for under a deferral health care program.</p> |

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| <p>41. Responsibilities according to OIG</p> | <ul style="list-style-type: none">• Oversight and implementation of Compliance Program (CP).• Reporting on a regular basis to governing body, CEO, and compliance committee• Revising compliance program as needed• Developing, coordinating, and participating in training and education• Ensuring contractors and agents are aware of CP requirements• Ensuring background checks are done• to eliminate sanctioned individuals and contractors• Assisting with internal compliance review and monitoring activities• Independently investigating and acting on matters related to compliance |
| <p>42. HCCA prepared and published Code of Ethic for Health Care Compliance Professional addressing 3 principles</p> | <ul style="list-style-type: none">• Principle 1 - Obligation to public• Principle 2 - Obligation to employing organization - should serve organization with highest sense of integrity, unprejudiced, and unbiased judgment• Principle 3 - Obligation to profession - uphold integrity and dignity of profession, to advance effectiveness of compliance program and to promote professionalism in health care compliance. |

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| <p>43. Compliance Committee</p> | <p>"to advise the compliance officer and assist in the implementation of the compliance program."</p> |
| <p>44. Function of Compliance Committee:</p> | <ul style="list-style-type: none">• Analyzing legal requirement and specific risk areas• Regularly reviewing and assessing policies and procedures• Assisting with the development of standards of conduct and policies and procedures• Monitoring internal systems related to standards, policies, and procedures• Determining the appropriate strategy to promote compliance• Developing a system to solicit, evaluate, and respond to complaints and problems |

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| <p>45. OIG suggest training be separated into two sessions:</p> | <ul style="list-style-type: none">• the first a general session on compliance for all employees and• the second covering more specific information for appropriate personnel |
| <p>46. OIG Work Plan</p> | <p>identifies high risk & key areas of focus for auditing</p> |

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| <p>47. Code of Conduct</p> | <p>must be distributed within 90 days of hire</p> |
| <p>48. OIG can impose mandatory exclusion for a minimum of</p> | <p>5 years</p> |

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| <p>49. Federal Sentencing Guidelines (FSG)</p> | <p>very clear on the expected board commitment</p> |
| <p>50. A teaching hospital may want their support for a compliance program</p> | <p>To come from the Dean</p> |

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| <p>51. Caremark International Derivative Litigation</p> | <p>makes the board responsible for implementation of a system to gather information on the company's efforts to prevent and detect fraud and abuse</p> |
| <p>52. FSG suggests offering</p> | <p>incentives to those who follow the compliance and ethics program</p> |