

HCCA's 12TH ANNUAL COMPLIANCE INSTITUTE

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**THE COMBINATION FOR A
COMPREHENSIVE COMPLIANCE PROGRAM
IN THE AMBULATORY SURGERY CENTER**

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Understanding ASCs

- Most ASCs are licensed by the state, certified by Medicare under Part B and accredited by one of several accrediting bodies (AAASC, JCAHO or other specialty accreditation organizations)
- ASCs provide only outpatient surgical and other procedures requiring up to a 23 hour stay and recognized by Medicare as being appropriate for an outpatient surgical setting
- ASCs are generally Stark-Exempt



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Understanding ASCs (cont'd)

- ASC covered procedures are those that generally do not exceed 90 minutes in length and do not require more than four hours recovery or convalescent time.
- The operating room(s) and recovery room(s) are to be used only for patients having surgery. The ASC must also have a separate recovery room and waiting area.
- An ASC may be either hospital-operated or independent. The hospital-operated ASC must be a separately identified entity distinct from the hospital.



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Unique Features of ASCs

- Often physician-owned or joint ventured with hospitals
- May be single specialty (GI, Ophtho) or multispecialty facilities (depends on ownership)
- Most are for profit businesses
- Have their own AKS safe harbors



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Legal Issues

- State and federal statutes, laws and regulations
- Compliance and disclosure issues
 - Physician ownership
 - Credentialing and peer review
 - Billing, coding and claims filing
 - Required for reimbursement
- HIPAA



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Anti-Kickback Issues

- Stark laws are generally inapplicable to ASC joint ventures
- Local and state anti-kickback laws may apply to:
 - Distributions to physicians
 - Relate to ownership interest
 - Do not relate to volume of referrals/use
 - Extension of practice analogy



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ASC Safe Harbors

- Physicians who refer to ASC must also perform the procedures
- Financial aspects not based on volume or value of referrals (anticipated or actual)
- One-third of physician income over 12 months comes from ASC procedures (income test)
- One-third of physician procedures performed over 12 months are at the ASC (procedure test)



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COMPLIANCE OVERVIEW

- Following the rules that govern your business.
- In Health Care industry - No small feat!
- Very complex and ever-changing legal and regulatory landscape
- Many different disciplines must work closely and collaboratively



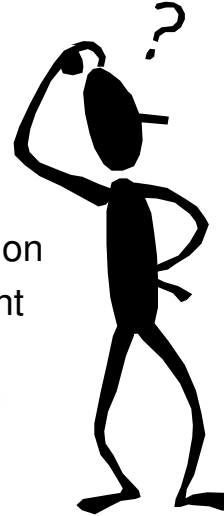
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WHY HAVE A COMPLIANCE PROGRAM?

- Provides legal protection from significant new legal liability
- Reduces likelihood of problems occurring
- Increases likelihood of early detection
- Mitigates consequences in the event of a violation
- Operational benefits: Practices and Policies in alignment



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GOAL OF THE COMPLIANCE PROGRAM

- TO IDENTIFY
 - areas of potential concern
 - types of problems and offenses likely to occur
 - areas of inconsistency in policy or operations

TO MINIMIZE RISK!



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CORE ELEMENTS OF A COMPLIANCE PROGRAM

- **CODE OF CONDUCT**
- Audits and Evaluation
- Education and Training
- Compliance Infrastructure (such as Reporting Processes, Policies and Procedures)



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MAJOR ELEMENTS OF COMPLIANCE PROGRAM

- Written policies and procedures
- Designation of a compliance officer and compliance committee
- Training and education
- Lines of communication
- Enforced standards based on publicized disciplinary guidelines



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MAJOR ELEMENTS OF COMPLIANCE PROGRAM

- Auditing and monitoring
- Prompt response to identified offenses/deficiencies
- Development of corrective action initiatives



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WHO IS INVOLVED?

- EVERYONE!
- All employees
- Management
- Practitioners
- Contract service providers
- Vendors
- Other healthcare partners
- Agents



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STEPS IN IMPLEMENTATION

- **Assess** organizational risks
- Determine gaps and build compliance infrastructure
- Establish standards of conduct
- Establish employee hotline for reporting of problems
- Train/educate employees
- Evidence program effectiveness (monitor and audit)
- Base improvements on results of audit



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THE ASSESSMENT PROCESS

- ASC compliance assessment is a form of due diligence
 - Facility issues (structural)
 - Operating issues (licenses and permits)
 - Survey reports (State Survey)
 - CLIA
 - Pharmacy
 - Accreditation



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SCOPE OF ASC COMPLIANCE ASSESSMENT PROCESS

- Ownership structure
- Governance structure
- Administrative structure
- Financial and billing structure
- MIS and medical records
- Medical and professional staff
- Other clinical staff



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DEVELOPING A CODE OF CONDUCT

- The cornerstone of the Compliance Program
- Defined in the Office of Inspector General (OIG) Guidelines
- Required by the Penalty Mitigation Factors under federal law
- Comply with policies and procedures
- Document accurately and completely
- Immediately report unethical behavior or illegal conduct to Compliance Committee/Officer



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YOU ARE EXPECTED TO...

- Create and maintain a culture that promotes the highest standards of ethics and compliance
- Encourage everyone to raise concerns when they arise
- Never sacrificing ethical and compliant behavior in the pursuit of business objectives
- Continue to providing high quality healthcare
- Be committed to compliance
- Support the compliance program objectives
- Cooperate with compliance initiatives



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YOU ARE EXPECTED TO...

- Be vigilant about conflicts of interest
- Avoid even the appearance of impropriety
- If you are not sure - ASK!
- Pay attention to detail, especially in areas relating to coding and billing



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YOU ARE EXPECTED TO...

- Ensure that the codes used accurately describe the services rendered
- Use Diagnosis and Procedural codes based on the medical record, other documentation, and supported by physician orders where appropriate
- Adequately document the great work you are doing



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YOU ARE EXPECTED TO...

- Preserve confidentiality of patient information and records
- Preserve confidentiality of business information and records
- Participate in training
- OBEY THE RULES THAT GOVERN YOUR BUSINESS!
- Be familiar with and obeying the Code of Conduct and related policies
- Become familiar with "Fraud and Abuse" laws
 - False Claims
 - Anti-Kickback
 - Physician Self-Referral



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YOU ARE EXPECTED TO...

- Report any instances of actual or suspected problems or non-compliance
- Cooperate fully with all internal reviews, investigations and audits
- Implement any corrective action that is warranted



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WHAT DO YOU REPORT?

- Any known or suspected violations of:
 - the Code of Conduct
 - policies and procedures
 - federal or state law or regulation
 - payor policy or procedure
 - healthcare industry best practices



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RELEVANT FEDERAL LAWS AND REGULATIONS AFFECTING ASCs

- Health Insurance Portability and Accountability Act of 1996
- Balanced Budget Act of 1997
- False Claims Act
- Fraud and Abuse - Criminal Liability
- Fraud and Abuse - Civil Liability
- State False Claims/Fraud and Abuse Laws
- Deficit Reduction Act of 2006



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OIG Work Plan- Fiscal Year 2008- Targets to watch:

- Place of service errors - OIG will determine whether physicians properly code place of services given differences in reimbursement between office and hospital setting
- Evaluation and management services during global surgery periods – OIG will audit the inclusion of E&M services during the global surgery service period defined in the “Medicare Claims Processing Manual,” Chapter 12, section 40



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OIG Work Plan- Fiscal Year 2008- Targets to watch:

- Medicare payments for interventional pain management procedures
- Increased investigation of individuals, facilities, or entities that bill Medicare for false claims
- Increased scrutiny of business arrangements
- Review of quality of care issues



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Published OIG Compliance Guidance Relevant to ASCs

- Billing for items or services not actually rendered
- Providing medically unnecessary services;
- Separate billing of DHS ancillaries
- Improper ownership and shareholder/member distributions or removals
- Corporate Integrity/Conflicts of Interest
- Outpatient services rendered in connection with inpatient stays
- Quality of care



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Published OIG Compliance Guidance Relevant to ASCs

- Duplicate billing
- False cost reports
- Unbundling
- Failure to refund credit balances to federal or state programs
- Improper incentives violative of anti-kickback statute, laws and regulations



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General Considerations in Developing a Compliance Plan for an ASC

- Compliance programs are required by the Deficit Reduction Act for Medicaid
- Formal compliance programs cost money and administrative resources
- There is no single form of compliance program - "one size does not fit all!"



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Special Considerations in Developing a Compliance Plan

- Are there other complicating factors such as other economic or ownership relationships among owners or users of the facility?
- Is the facility single specialty, multi-specialty, and/or include other ancillary services?
- What is the current audit and enforcement activity of regulators in the geographic area?



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In Developing a Compliance Plan, Look at the...

- Size of organization (owners, employed staff, medical/professional staff)
- Complexity of its operations and regulatory responsibilities
- Ability to develop and implement a plan
- Ability and commitment to comply with the plan
- Confidence in systems, procedures and people
- Tolerance for risk-taking



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Include in the Plan...

- the authority, responsibility and delegation
- the target areas
- document review and process for revision
- recruitment and personnel standards
- training and communication
- reporting systems
- periodic audits
- enforcement and discipline
- documentation of the program



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Practical Considerations to Designing a Program

- In small organizations, the board must still authorize and oversee compliance
- The CO does not have to be recruited from outside the business
- Don't abrogate responsibility for compliance to an outside vendor (e.g. billing company)
- Identify risks in advance of implementing a compliance program



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Practical Considerations to Designing a Program

- Review corporate documents, policies and procedures, bylaws, etc. for consistency with compliance program
- Beware of “window dressing” a compliance program
- Use “due diligence” in hiring practices
- Look for opportunities to share training programs and information
- Make communication and reporting process easy
- Use care in audit process and act on results



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QUESTIONS?

THANK YOU!

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