Business Ethics and Compliance

Health Care Association of New Jersey
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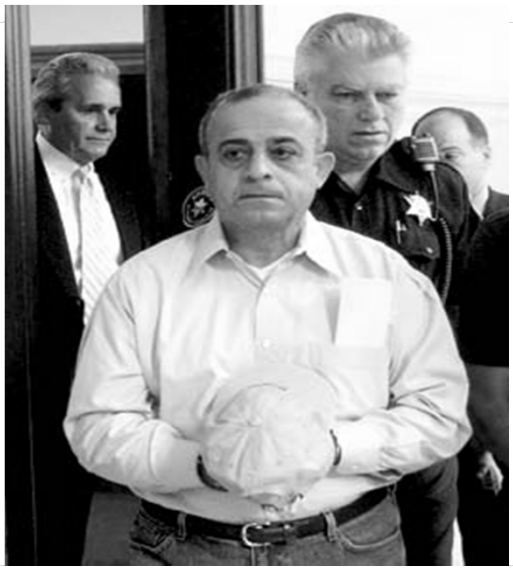

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Corporate Meltdowns/Scandals

- Madoff
- Enron
- WorldCom
- Global Crossing
- Adelphia
- General Electric
- Tyco
- Real Estate Bubble
- Lehman Brothers
- Bank of America

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Corporate Meltdows/Scandals

- Healthcare? AHERF, Novacare, Vencor, St. Francis, United Hospitals, Genesis Health, Magellan, Health South, HCA
- Seemingly Endless Cases

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Why Consider a Compliance Plan

- **Government Enforcement and Mandates**
- **Government Hysteria**
- **Private Payor Enforcement Actions**
- **Qui Tam/Whistleblower Cases**
- **Sentencing Guidelines**
- **Following the Herd**

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Significant Concerns Raised By Congress

- accounting irregularities/perceived lack of independence of auditors
- conflicts of interest
- inadequate monitoring by the board
- breaches of fiduciary duty by directors and officers
- excessive executive compensation

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Sarbanes-Oxley Act of 2002

- applies to publicly traded companies
- will it become the standard for all entities?
- is a compliance system in place to verify the financial statements, cost reports, etc.?

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Sarbanes-Oxley Requirements

- **Certification of Financial Statements**
  - **Criminal and civil liability**
  - **Medicare cost reports analogy**
    Audit Committee
- **Prohibition on CPA Firms Providing Audit and Significant Other Services**
- **Certain Loans to Executive Officers and Directors**
- **Whistleblower Protections**
- **Altering and Preserving Documents**

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Types of Risk

- Bribery and Corruption.
- Antitrust and Unfair Competition.
- Privacy and Data Security.
- Harassment and Discrimination.
- Human Rights.
- Conflicts of Interest.
- Environment, Health, and Safety.
- Whistleblower Protection.
- Political Lobbying.
- Theft, Embezzlement, and Other Financial Misconduct.
- Fraud and Earnings Management.
- Money Laundering.

Source: "The Ethics and Compliance Handbook: A Practical Guide from Leading Organizations" Ethics and Compliance Officer Association Foundation (2008).

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Compliance Plan Benefits

- **Can Help to Prevent Compliance Problems or Identify Problems at Earlier Stage**
- **Reduces Potential Criminal Penalties Under Federal Sentencing Guidelines**

Example: $2,000 Loss, "False Claims" Conviction:

Compliance Program	Minimum Fine	Maximum
No	$40,000	$80,000
Yes	$16,000	$32,000

- **Can Help to Show Lack of Fraudulent Intent in Civil False Claim Case**

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Why Not Consider a Compliance Plan?

- **Cost of Designing**
- **Cost of Implementation**
- **My Organization is Well Run and Intentioned**
- **Risk of Not following Plan**
- **Staff Are Well-Trained and Loyal**
- **It is a Fad**
- **Difficulty in Terminating the Plan**
- **Audit Roulette**

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Mandatory Compliance Program

- PPACA* mandates that NFs/SNFs must have a compliance & ethics program in operation that is effective in preventing and detecting criminal, civil, and administrative violations and in promoting quality of care, consistent with regulations developed by HHS and OIG **by March 23, 2013,** as condition of Medicare / Medicaid enrollment
  - HHS has not yet finalized regulations for mandatory compliance & ethics programs
  - As of February 2011, HHS indicated that it would be issuing a proposed rule concerning the mandatory compliance & ethics program "at a later date"
- Currently, New Jersey does not require Medicaid providers to have a compliance program; yet encourages Medicaid providers to have such a program in place, especially if payments from the Medicaid program exceed $100,000 per year.
- Facilities are best served to have compliance & ethics program in place that meet existing OIG guidance and that may be modified to meet the new requirements once issued. Existing Guidance:
  - OIG Compliance Program Guidance for NFs (March 16, 2000)
  - OIG Supplemental Compliance Program Guidance (Sept. 30, 2008)

*Patient Protection and Affordable Care Act.

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Mandatory Compliance Program

- Fundamental Elements of a Compliance Program
  - Written policies and procedures
  - Compliance professionals (i.e., Chief Compliance Officer & Committee)
    - Must use due care not to delegate substantial discretionary authority to individuals whom the facility knew, or should have known through the exercise of due diligence, had a propensity to engage in criminal, civil, and administrative violations
  - Effective training of all executives and employees
  - Effective communication process / mechanism for reporting (allowing for anonymous and good faith reporting of potential compliance issues as they are identified)
  - Internal monitoring (internal / external audits)
  - Enforcement of standards / disciplinary policies for failing to report suspected problems; engaging in non-compliant behavior; encouraging, directing, facilitating or permitting either actively or passively non-compliant behavior.
  - Prompt response / corrective actions

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Mandatory Compliance Program

- FERA* and PPACA also demand a proactive approach with respect to compliance and ethics programs
  - Diligent contract management
    - Ensure no payments to physicians absent signed writing (unless employee)
    - Capture when agreements expire
    - Documentation of all payments passing between facility and physicians
  - Adequate accounting procedures
  - Adequate monitoring / auditing of billings, payments, medical necessity, quality of care (to promptly identify overpayments)
  - Potential development of specialized compliance committee
    - Involvement of key players: general counsel, compliance officer, administration, accounting and those responsible for physician contracting
  - Ensure standardized process for reporting, investigation and resolution of potential compliance issues
    - Ensure prompt resolution with complete documentation of all measures to resolve issue

*Fraud Enforcement and Recovery Act.

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WHY HAVE A COMPLIANCE PROGRAM?

- "An effective compliance program demonstrates a nursing facility's good faith effort to comply with applicable statutes, regulations, and other federal health care program requirements, and may significantly reduce the risk of unlawful conduct and corresponding sanctions."

OIG Guidance for nursing facilities issued September 30, 2008

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Ongoing Risk Assessment

- What are Current Controls?
- How effective are they?
- What is company exposure?

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Organizational Factors

- Size of the organization.
- Nature of the industry or sector.
- Organization structure.
- Leadership and governance.
- Workforce composition.
- External legal, regulatory, and political environment.
- Physical environment.
- Geographical dispersion of employees.
- Vulnerability to catastrophic events, including terrorism.
- History of claims, litigation, and external inquiries.
- How allegations or violations are handled once brought to light.

Source: "The Ethics and Compliance Handbook: A Practical Guide from Leading Organizations" Ethics and Compliance Officer Association Foundation (2008).

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STEPS

- Identify
- Classify
- Prioritize

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PHASES

- Risk Management Team.
- Risk Identification & Data Gathering.
- Gap Analysis.
- Prioritization & Mitigation.
- Results.
- Monitoring & Reassessment.

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Employee Questions

- What is the single most compelling risk facing our organization today?
- What factors helped you identify this risk?
- Name other compelling risks that face our organization and your operations.
- What factors helped you identify these risks?
- What might help reduce the damage that these risks might cause?
- How effective is our organization (and your business unit) in reducing the damage that these risks might cause?
- Are there any risks facing the organization that "keep you up at night?
- What kinds of risks could emerge in the next two years that could harm our organization.

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Common Elements

- Written code of conduct
- Compliance officer
- Training and education
- Communication
- Auditing and monitoring
- Discipline/enforcement
- Corrective action plan

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Code of Conduct Principles

- A code should establish an organization's overall commitment to ethics and compliance and reflect its values and mission.
- A code should explain both what the organization expects of its employees' business conduct and, in turn, what employees can expect from their organization.
- A code should communicate an organization's values clearly and succinctly.
- A code's provisions should address the organization's key risk areas.

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Code of Conduct Sections

- Introductory letter from senior management.
- Mission statement, statement of values, and guiding principles.
- Ethical decision-making framework.
- How to seek advice and report misconduct.
- Substantive rules and guidance.
- Disciplinary rules and enforcement procedures.
- Protection against retaliation.
- Acknowledgment or certification process.

Source: "The Ethics and Compliance Handbook: A Practical Guide from Leading Organizations" Ethics and Compliance Officer Association Foundation (2008).

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Code of Conduct Principles Continued:

- A code should cover the conduct required by law, regulation, policy and ethical principle.
- A code should address the behavior required of personnel at every level of the organization, including executives, managers, and employees, as well as board members.
- Prior to adoption, the code should be reviewed by a wide spectrum of personnel and be seen as a living document.
- A code should be updated regularly to ensure it addresses an organization's current risks, culture, operations, and business environment.

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Senior Management Role

- Publicly declaring that ethics and integrity are among the organization's key business objectives.
- Serving as a model of ethical business conduct.
- Discussing current ethics and compliance issues at employee fora.
- Discussing personal ethical challenges and sharing their resolution.
- Asking subordinates about ethics and compliance issues on a regular basis.
- Using ethics and integrity as criteria in determining compensation and promotion.

Source: "The Ethics and Compliance Handbook: A Practical Guide from Leading Organizations" Ethics and Compliance Officer Association Foundation (2008).

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Senior Management Role Continued:

- Participating in ethics and compliance educational programs, such as management or leadership development programs.
- Ensuring consistent discipline of all personnel, especially the most senior managers and best performers, if they violate organizational rules, policies, or norms.
- Publicly encouraging employees to raise ethics and compliance issues and taking decisive action to prevent and respond to retaliation.
- Communicating honestly with employees about the organization's ethics and compliance successes as well as its failures.
- Reflecting on lessons learned for future ethics and compliance efforts.

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Compliance Office Skill Set

- Working well as a team-member or collaborator.
- Listening empathetically.
- The courage to "do the right thing" even when it is likely to be unpopular.
- Political and diplomatic savvy.
- Discretion in handling confidential matters.
- Ability to build trust throughout the organization.
- Understanding organizational processes and relationships.
- Making smart decisions in a timely manner, even when information is incomplete or deadlines are tight.
- Ability to manage change and bring others along in the process.
- Strong working knowledge of business law and regulation (e.g., Medicare, Medicaid, DOH).
- Cultivation of productive relationships with subordinates, peers, and superiors.

Source: "The Ethics and Compliance Handbook: A Practical Guide from Leading Organizations" Ethics and Compliance Officer Association Foundation (2008).

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Compliance Committee Role

- Assisting the board of directors, its audit committee, and senior management in establishing a risk assessment for the organization and fulfilling their responsibilities to exercise reasonable oversight for ethics and compliance.
- Establishing an ongoing ethics and compliance strategy that defines priorities and includes a process for reviewing and updating the strategy at regular intervals.
- Developing minimum standards and expectations for the organization's ethics and compliance program and periodically evaluating the program's effectiveness.
- Reinforcing the importance of the role of senior leadership in communicating the organization's commitment to ethical business conduct (e.g., "tone from the top").

Source: "The Ethics and Compliance Handbook: A Practical Guide from Leading Organizations" Ethics and Compliance Officer Association Foundation (2008).

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Compliance Committee Role Continued:

- Promoting an organizational culture that encourages ethical conduct and a commitment to compliance with the law.
- Monitoring legal and regulatory developments in the organization's external risk environment.
- Facilitating periodic review of the organization's ethics and compliance risk assessments.
- Reviewing and approving organizational ethics and compliance policies.
- Recommending and facilitating communications and training.
- Reviewing disciplinary actions for consistency.

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Organize the Compliance Function

- **Independent Department Ensures Unbiased Efforts -- Well Received by Gov't Thus Far**
- **Chief Compliance Office Must Report Directly to President/CEO and/or Board of Directors**
- **Compliance Department Implements Anonymous Phone "Hotline" and Post Office Box for Employee Reporting**
- **Compliance Department Responsible for All Compliance Functions**

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Training Topics

- Introduction to the code of conduct.
- Calling the hotline or helpline.
- Conducting internal investigations (for targeted personnel only).
- Preventing retaliation.
- Ethical decision-making.
- Distinguishing between values-based and rules-based compliance.
- Refresher training on the code of conduct and key substantive areas (e.g., insider trading, conflicts of interest, harassment, or discrimination).

Source: "The Ethics and Compliance Handbook: A Practical Guide from Leading Organizations" Ethics and Compliance Officer Association Foundation (2008).

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Principles of Disclosure

- Employees should be actively encouraged to seek ethical guidance and report suspected wrongdoing.
- Every employee should be informed of the advice and reporting system.
- The advice and reporting functions must be viewed by employees as independent of management, unbiased, and trustworthy.
- Employees who come forward with ethics and compliance issues must be assured that their concerns and, where requested, identity will be kept confidential to the extent practicable.

Source: "The Ethics and Compliance Handbook: A Practical Guide from Leading Organizations" Ethics and Compliance Officer Association Foundation (2008).

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Principles of Disclosure continued:

- Employees should be able to seek advice and make reports anonymously.
- Retaliation of any kind against employees who make good-faith reports of ethical or legal violations cannot be tolerated—and must not be perceived as being tolerated.

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Portals of Disclosure

- A dedicated telephone helpline (where technology is employed to protect anonymity).
- A dedicated fax number.
- A dedicated Web-portal or e-mail inbox.
- Personal phone call or meeting with specific members of the ethics and compliance team.
- An organization ombudsman.
- Specific members of the human resources team.
- Direct supervisors and managers.
- Specific members of the general counsel's office.
- Internal or external auditors.
- Designated members of the audit committee of the board of directors.

Source: "The Ethics and Compliance Handbook: A Practical Guide from Leading Organizations" Ethics and Compliance Officer Association Foundation (2008).

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Example of Effective Reporting System

Individual Places Call to Hotline → **Anonymous Confidential Number is Assigned as Well as Date and Time for Follow-up** → **Report is Relayed to Individual Trained by Counsel and Recorded on Appropriate Form Marked "Intended for Immediate Transmission to Counsel"**

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Example of Effective Reporting Systems (Cont'd)

Report is Investigated → **Follow-up Interview is Conducted With Reporting individual** → **Take Appropriate Action Based on Compliance Plan and Advice of Counsel**

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Internal Investigations

- Conduct intake.
- Screen for scope.
- Assess seriousness of the allegation and conduct risk and legal analysis.
- Determine the laws or policies at issue.
- Assign the matter to investigator(s).
- Develop an investigation plan.
- Assemble and review relevant documents.
- Notify employees and others to be interviewed.
- Conduct interviews.
- Document the investigation.
- Reach a conclusion.
- Communicate with management.
- Close the investigation.

Source: "The Ethics and Compliance Handbook: A Practical Guide from Leading Organizations" Ethics and Compliance Officer Association Foundation (2008).

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Identifying Serious Compliance Issues

- **Conduct is Systemic in Nature**
- **Many Claims or Claims over Long Time Period at Issue**
- **Potential for Allegations of Intentional or Reckless Wrongdoing**
- **High Level Management Personnel Implicated**
- **Direct or Indirect Economic Benefit to Persons Involved**
- **If One or More of Above, Treat as Serious and Call In Independent Outside Counsel**

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Investigating Serious Compliance Issue

- **Ensure That Investigation Results Remain Privileged (Attorney-Client and Attorney Work-Product Privileges)**
- **Conduct Investigation for Purpose of Assisting Counsel in Providing Legal Advice**
- **Treat All Communications as Highly Confidential**
- **For Lower Level Employees, Ensure that Their Communications are at Direction of Corporate Superiors For Purpose of Securing Legal Advice**
- **Ensure Communications With Employees Concern Matters Within Scope of that Employee's Responsibility, and Not Available from Higher Level Management (Speak with Most Responsible Person Available)**

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False Report Issues

- Has the employee submitted multiple complaints in the past?
- Is there a long-running dispute between the employee and the subject of the report?
- Has the employee tried to escalate a private dispute into a work-related controversy?
- Is the employee facing some type of disciplinary action or has he or she recently received a poor performance evaluation?
- When pressed, can the caller provide factual support for his or her allegations, or does he or she revert to broad, unsubstantiated statements such as "Everyone knows that…"?
- Has the employee embellished the story?

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AUDITS: How Far Back Should You Go?

- Great question, no great answer
- Contemporaneous review
- Risk analysis
  - "should have known" standard
    - liability for retaining overpayments
      - risk of whistle blower
        - risk of government Investigations

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Reporting and Monitoring

- **Complete Computer Database**
- **Track All Employee Training -- Must be Able to Prove the Training Given**
- **Track Hotline Contacts, Investigation Results and Responsive Measures**
- **Full Reporting Capability to Ensure Key Decision Makers Have Access to Data and Act on it -- Shows Program is Active and Effective**

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Overpayments

- Overpayments from the Medicare and Medicaid programs must be reported and returned **within 60 days** of the later of:
  - the identification of the overpayment, OR
  - the date any corresponding cost report is due.
- The overpayment must be reported and returned to either CMS, Medicaid, the intermediary, carrier or contractor, with a written explanation of the reason for the overpayment.

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Overpayments

- Inaccurate cost reports
- Duplicate payments of the same services
- Payment for non-covered, non-medically necessary services
- Services not actually rendered (i.e., acuity audits)
- Payment made by a primary insurance
- No order for service
- Excluded ordering or servicing person
- Service by unenrolled provider
- Service by person lacking required license or certification
- Service inconsistent with physician order or treatment plan
- Service not documented as required by regulation

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Overpayments

- Penalties for Retention of Overpayments:
  - Retention of overpayment → "obligation" for the purposes of FCA
  - PPACA also amended the Civil Monetary Penalty ("CMP") Statute to increase CMPs for retention of overpayments
    - May subject the Facility to CMPs of not more than $10,000 for each item or service, plus not more than three times the amount claimed for each such item or service.
  - The Facility may be excluded from participation in Medicare / Medicaid.
  - Potential liability under New Jersey False Claims Act.

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Overpayments

- Open Questions:
  - "Identified" is not defined
    - Compare with CMS proposed rule in 2002 (which was never adopted) that required reporting and return of Medicare overpayments within 60 days of identifying *or learning of* it.
    - The deletion of "learning of" from the PPACA provision may indicate an intent to apply the PPACA provision to situations where a provider has confirmed the existence and scope of the overpayment.
    - However, NY OMIG has taken the position that "identified" means that the fact of an overpayment, not the amount of the overpayment, has been identified.
  - Overpayment is defined to include any funds that a provider receives or retains from Medicare or Medicaid to which the provider, after applicable reconciliation, is not entitled; although "after applicable reconciliation" not defined
    - Potential argument that such reconciliation allows for time to complete an investigation prior to reporting and returning an overpayment.

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Overpayments

- In New Jersey, the New Jersey Office of the State Comptroller - Medicaid Fraud Division (MFD) has developed a self-disclosure protocol to include (but not limited to) the reporting, explanation and return of overpayments within 60 calendar days of identification
  - Available at http://nj.gov/njomig/disclosure
  - Recommends use of Provider Self-Disclosure Form
- Per the MFD, the benefits to providers who, in good-faith, participate in a self-disclosure, include:
  - Avoidance of FCA penalties if reported within 60 days of identification
  - Forgiveness or reduction of interest payments (for up to two years)
  - Extended repayment terms
  - Waiver of penalties and/or sanctions
  - Timely resolution of the overpayment
  - Decrease in the likelihood of imposition of an MFD Corporate Integrity Program

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OIG Workplan 2013

- In 2013, OIG has identified the following LTC areas for review:
  - Whether payments to SNFs meet Medicare coverage requirements
  - Whether SNFs have addressed certain Federal requirements related to quality of care, including whether SNFs
    - developed plans of care based on assessments of beneficiaries
    - provided services to beneficiaries in accordance with the plans of care, and
    - planned for beneficiaries' discharges
  - Adverse events in Post-Acute Care for Medicare beneficiaries
  - NFs compliance with assessment and care planning requirements for residents receiving atypical antipsychotic drugs
  - Oversight and enforcement against poorly performing NFs
  - Hospitalizations of residents
  - Verification of nursing homes' correction of deficiencies cited by State surveyors
  - Medicare Part B Services During Non-Part A Nursing Home Stays
  - Oversight of Minimum Data Set submissions
  - Communicable Disease Care

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Major Legal Issues

- Quality of care
- Kickbacks
- Discounts
- Dealings with excluded parties
- Billing and coding issues
- Patient rights
- Mental health services
- Physician certifications
- Co-pays
- Billing for Unnecessary Services
- Billing for Services Not Rendered
- Billing for Services Provided by Unqualified Personnel
- Misrepresentation of the Nature of Services Provided

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Other Issues to Consider

- HIPAA and Privacy
- Independent Review of Political Contributions
- Legal Review of All Contracts
- Appropriate Employee Compensation Mechanisms
- Anti-Trust Issues (Price-fixing, Boycotts, Market Allocation)
- Conflicts of Interest
- Tax Exemption Issues
- OSHA, ADA, Wage and Hour

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OIG Guidance
For Nursing Facilities
Issued September 30, 2008

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PURPOSE

- Voluntary Guidelines to assist nursing facilities in identifying significant risk areas and evaluating and refining ongoing compliance efforts

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WHY ISSUE?

- Significant changes in the way nursing facilities deliver and receive reimbursement for health care services and increased concerns about quality of care in nursing facilities

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FRAUD AND ABUSE RISK AREAS

- Quality of Care.
- Accurate Claiming.
- Federal Anti-Kickback Statute.
- HIPAA Privacy and Security Rules.
- Other Risk Areas.

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QUALITY OF CARE RISK ISSUES

- Sufficient Staffing.
- Comprehensive Care Plans.
- Medication Management.
- Appropriate Use of Psychotropic Medications.
- Residents Safety.

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SUFFICIENT STAFFING

- No model will suit every facility.
- NF's are strongly encouraged to assess their staffing patterns regularly for sufficient competent staff to care for unique acuity level of residents.

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STAFFING CONSIDERATIONS

- Resident case mix.
- Staff skill levels.
- Staff to resident ratios.
- Staff turnover.
- Staffing schedules.
- Disciplinary records.
- Payroll records.
- Timesheets.
- Adverse event reports.
- Interviews with staff residents and/or family.
- Assess staffing to measure actual "on the floor" staff rather than "on paper" staff.

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Comprehensive Resident Care Plans

- Interdisciplinary and comprehensive approach.
- Involving residents and responsible parties.
- Involvement of attending physicians in meetings or otherwise.
- Avoid risk of inadequate care, medically unnecessary or medically inappropriate services.

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MEDICATION MANAGEMENT

- Stresses role of consulting pharmacist.
- Processes to advance resident safety, minimize adverse drug interaction and correct irregularities in resident's drug regimen.

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PSYCHOTROPIC MEDICATIONS

- Avoid chemical restraint
- Avoid unnecessary drug usage.
- Collaboration between attending physician, medical director and consulting pharmacist to analyze the outcomes

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RESIDENT SAFETY

- Avoid mistreatment, neglect and abuse of residents
- Staff to resident
- Resident to resident
- Injuries of unknown origin
- Proper investigation and reporting
- Education on confidential reporting opportunities
- Encourages specialized training on recognizing abuse and neglect
- Staff screening and background checks and proper orientation and competency evaluation
- Goal: Prevent, investigate and respond appropriately

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ACCURATE CLAIMS SUBMISSION

- Common Risks
  - Duplicate billing
  - Insufficient documentation
  - False or fraudulent cost reports
- RUGS upcoding; case mix training is stressed
  - Periodic Internal and external validation of data is encouraged

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THERAPY SERVICES

- Potential false claims
- Improper utilization tied to RUGS level
- Overutilization of services billed under Part B
- “stinting” services to residents in a Part A stay
- Recommends complete and contemporaneous documentation by outside vendor of therapy services, periodic reconciliation with physician orders, interviews to confirm services delivered, necessity review during care planning.

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SCREEN FOR EXCLUDED INDIVIDUALS AND ENTITIES

- No payment may be made for services or items furnished by an excluded individual or entity
- OIG strongly advised NF's screen all owners, officers, directors, employees, contractors and agents against OIG's list of excluded individuals/entities on OIG website and US General Services Administrations excluded parties list system

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RESTORATIVE AND PERSONAL CARE SERVICES

- Include ulcer avoidance, ROM, ambulation, falls, incontinence and ADLs
- Must be delivered to avoid concern that billing for such programs is "fraudulent" due to inadequate services.
- Interviews and periodic evaluations recommended.
- Complete and contemporaneous documentation is critical

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ANTI-KICKBACK STATUTE

- Criminal prohibition against renumeration (in any form, whether direct or indirect) made purposefully to induce or reward the referral or generation of federal health care program business
- Liability is determined separately for each party involved
  - Potential cross-referrals;
  - Hospices;
  - DME Companies;
  - Laboratory;
  - Diagnostic Testing Facilities;
  - Long Term Care Pharmacies;
  - Hospitals;
  - Physicians;
  - Other Nursing Facilities;
  - Physical Occupational and Speech Therapists.

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Anti-kickback Evaluation

- Recommended internal questions:
- Does the nursing facility (or its affiliates or representatives) provide anything of value to persons or entities in a position to influence or generate Federal health care program business for the nursing facility (or its affiliates) directly or indirectly?
- Does the nursing facility (or its affiliates or representatives) receive anything of value from persons or entities for which the nursing facility generates Federal health care program business, directly or indirectly?
- Could one purpose of an arrangement be to induce or reward the generation of business payable in whole or in part by a Federal health care program?
- Importantly, under the anti-kickback statute, neither a legitimate business purpose for an arrangement nor a fair-market value payment will legitimize a payment if there is also an illegal purpose (i.e., inducing Federal health care program business).

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Aggravating Considerations

- Does the arrangement or practice have a potential to interfere with, or skew, clinical decision-making?
- Does the arrangement or practice have a potential to increase costs to Federal health care programs or beneficiaries?
- Does the arrangement or practice have a potential to increase the risk of overutilization or inappropriate utilization?
- Does the arrangement or practice raise patient safety or quality of care concerns?
- Does the arrangement meet a safe harbor under the regulations?

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Facts and Circumstances Considerations

- Nature of the relationship between the parties.
- Manner in which participants were selected.
- Manner in which the remuneration is determined.
- Value of the remuneration
- Nature of items or services provided
- Potential Federal program impact.
- Potential conflicts of interest.
- Manner in which the arrangement is documented.

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Risk Areas

- Free goods and services
- Pharmaceutical Consultant Services
- Medication Management of supplies offered by a Pharmacy
- Infection Control, Chart Review, or other services offered by laboratories or other suppliers
- Equipment, computers or software applications that add independent value to the nursing facility
- DME or supplies offered by DME suppliers for patients covered by the SNF Part A benefit
- A laboratory phlebotomist providing administrative services
- A hospice nurse providing nursing services for non-hospice patients
- A registered nurse provided by a hospital

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RISK AREAS (CONT:)

- Services contracts for nonphysician services
  - Periodically review contractor and staff arrangements to ensure that: (i) There is a legitimate need for the services or supplies; (ii) the services or supplies are actually provided and adequately documented; (iii) the compensation is at fair-market value in an arm'slength transaction; and (iv) the arrangement is not related in any manner to the volume or value of Federal health care program business.
  - Implement policies and procedures to minimize the risk of improper pharmaceutical decisions tainted by kickbacks.
  - Drug switches should only be in best interest of resident.

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RISK AREAS (CONT:)

- Physician Services
  - Medical director oversight but no compensation for referrals
  - Fair market value, bona fide services received
  - No excessive number of medical directors
  - Use personal services safe harbor whenever possible

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RISK AREAS (CONT:)

- Discounts
  - Price reductions permitted when in the form of a price reduction, properly documented and disclosed as such on cost report.

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RISK AREAS (CONT:)

- No "swapping," i.e. accepting a low price from a supplier or provider on an item or service covered by the nursing facility's Part A per diem payment in exchange for the nursing facility referring to the supplier or provider other Federal health care program business, such as Part B business excluded from consolidated billing, that the supplier or provider can bill directly to a Federal health care program.
- Appropriate question to ask is whether the discount is tied or linked, directly or indirectly, to referrals of other Federal health care program business. Suspect arrangements include below-cost arrangements or arrangements at prices lower than the prices offered by the supplier or provider to other customers with similar volumes of business, but without Federal health care program referrals.
- Other suspect practices include, but are not limited to, discounts that are coupled with exclusive provider agreements and discounts or other pricing schemes made in conjunction with explicit or implicit agreements to refer other facility business.

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RISK AREAS (CONT:)

- Hospice arrangements
  - See new hospice conditions of participation for guidance on hospice interactions with skilled nursing facilities.
  - A hospice offering free goods or goods at below-fairmarket value to induce a nursing facility to refer patients to the hospice;
  - A hospice paying room and board payments to the nursing facility in excess of what the nursing facility would have received directly from Medicaid had the patient not been enrolled in hospice. Any additional payment must represent the fair-market value of additional services actually provided to that patient that are not included in the Medicaid daily rate;
  - A hospice paying amounts to the nursing facility for additional services that Medicaid considers to be included in its room and board payment to the hospice;

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RISK AREAS (CONT:)

- A hospice paying above fair-market value for additional services that Medicaid does not consider to be included in its room and board payment to the nursing facility;
- A hospice referring its patients to a nursing facility to induce the nursing facility to refer its patients to the hospice;
- A hospice providing free (or below fair-market value) care to nursing facility patients, for whom the nursing facility is receiving Medicare payment under the SNF benefit, with the expectation that after the patient exhausts the SNF benefit, the patient will receive hospice services from that hospice; and
- A hospice providing staff at its expense to the nursing facility.

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RESERVED BED PAYMENTS

- Payments should not be determined in any manner that reflects the volume or value of existing or potential referrals of Federal health care program business from the nursing facility to the hospital.
- Suspect arrangements include:
  - Payments that result in double-dipping by the nursing facility (e.g., sham payments for beds that are actually occupied or for which the facility is otherwise receiving reimbursement);
  - Payments for more beds than the hospital legitimately needs;
  - Excessive payments (e.g., payments that exceed the nursing facility's actual costs of holding a bed or the actual revenues a facility reasonably stands to forfeit by holding a bed given the facility's occupancy rate and patient acuity mix).
- Reserved bed arrangements should be entered into only when there is a bona fide need to have the arrangement in place. Reserved bed arrangements should serve the limited purpose of securing needed beds, not future referrals.

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Physician Relationships

- Stark Law must be considered for Self-Referrals
- Does Doctor have financial relationship with NF?
- Does NF provide designated health services (DHS) such as Lab., PT/OT billed to Part B?
- Evaluate need for signed, written agreement
- Document fair market value of compensation
- Evaluate other financial arrangements such as nonmonetary compensation

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Risk Areas Anti-Supplementation

- Medicare and Medicaid issue
- Concern about additional payments simply because the Medicare or Medicaid rate is too low
- NF may not charge more for covered items and services

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Risk Areas Part D Compliance

- Role of nursing facility staff when residents are selecting a Part D plan. Providing complete and objective education versus selecting for the resident.
- No remuneration for a resident selecting a particular plan
- NF must assure beneficiary's freedom of choice

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