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Compliance, Fraud and Abuse

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- Introduction
- Health Care Reform
  - Fraud and Abuse
    - False Claims Act
    - Overpayments
    - Stark Law Self-Disclosure Protocol
    - Anti-kickback Statute
    - Suspension of payments based on allegations of fraud and abuse
  - Medicaid Integrity Provisions
    - Expansion of Medicaid RAC activities
    - Mandatory Screening Requirements
    - Mandatory Exclusion
  - Long-term Care Compliance, Transparency and Accountability
    - Elder Justice Act
    - Mandatory Compliance and Reporting Requirements

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- Fraud Enforcement and Recovery Act of 2009 ("FERA"), enacted May 20, 2009.
- Patient Protection and Affordable Care Act ("PPACA") enacted March 2010, as amended by the Health Care and Education Reconciliation Act of 2010, enacted March 2010 ("HCERA").

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- FERA signed into law on May 20, 2009
  - Expands the scope of liability under the False Claims Act ("FCA"), which imposes liability for making false statements or claims for reimbursement to the government
  - FERA expands definition of "obligation" in the FCA to include the *retention* of any *overpayments*
  - Tracking mechanisms now key

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- Prior to FERA, liability existed under the FCA when a person "knowingly makes, uses or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government"
- FCA liability now broadened to include any false or fraudulent claim for government money or property
  - Regardless of whether the claim is presented to a government official or employee (may be claim presented to a contractor, grantee or other recipient if the money/property is to be spent or used on the government's behalf or to advance a government program / interest).
  - Regardless of whether the government has physical custody of the money
  - Does not consider the defendant's intent

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- PPACA signed into law by President Obama on March 23, 2010
  - Focus upon coverage expansion, quality improvement and cost efficiencies → subsidizing Federal healthcare programs
  - Reform affecting the health insurance industry and implementation of new consumer protections prohibiting prior practices of health insurers
  - Enhanced Medicare & Medicaid Program Integrity provisions
  - New requirements for long-term care compliance, transparency, accountability and reporting
  - Increased funding for investigation of fraud and abuse

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- 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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- 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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- 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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- 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.

- 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

- As recognized by the MFD, however, not all overpayments may warrant self-disclosure through the MFD protocol
- Providers must determine whether the repayment of the overpayment should be through self-disclosure or whether it would be better handled through administrative billing processes (i.e., voiding or adjusting the amounts of claims). Factors to consider include the:
  - exact issue
  - amount involved
  - any patterns or trends that the problem may demonstrate within the provider's system
  - period of non-compliance
  - circumstances that led to the non-compliance problem
  - organization's history
  - whether or not the organization has a corporate integrity agreement (CIA) in place

- Per MFD, issues appropriate for disclosure may include, but are not limited to:
  - Substantial routine errors
  - Systematic errors
  - Patterns of errors
  - Potential violation of fraud and abuse laws
- MFD suggests that providers consider obtaining the advice of experienced healthcare legal counsel or consultants in connection with evaluating the proper return of an overpayment.

- PPACA required establishment of a Self-Referral Disclosure Protocol for self-disclosure of Stark violations to CMS
  - http://www.cms.gov/PhysicianSelfReferral/65_Self_Referral_Disclosure_Protocol.asp#TopOfPage
- Under the SRDP, CMS may (but is not required to) compromise claims in settlement, based on the following factors:
  - Nature and extent of the improper practice
  - Timeliness of the self-disclosure
  - Cooperation in providing additional information
  - Litigation risk associated with matter disclosed
  - Financial position of the disclosing party
  - Such other factors as HHS/CMS considers appropriate

- A financial relationship exists with a referring physician and no exception applies or a technical violation (i.e. unsigned writing, expired contract)
  - Quantify payments at issue
    - Risk of $15,000 CMP per claim even if amount of payment is low
    - Large amount may attract whistleblower (increasing trend of physician whistleblowers)
  - Determine period of disallowance
    - When did relationship fall out of compliance?
    - When where claims illegally submitted for reimbursement?

- PPACA also makes changes to the enforcement of the Federal Anti-kickback Statute ("AKS") by eliminating the intent requirement
  - A person may now violate the AKS without actual knowledge of AKS or a specific intent to commit a violation
- Claims that include items or services resulting from an AKS violation trigger liability under the FCA
  - These changes will likely result in more aggressive enforcement of AKS violations as primary violations
  - AKS violations risk criminal liability

- In addition to existing penalties, PPACA authorizes HHS or the States, in consultation with the OIG, to suspend Medicare and Medicaid reimbursement "**pending an investigation of a credible allegation of fraud**," effective March 25, 2011.
- ***Credible allegation of fraud*** - an allegation from *any source*, including but not limited to the following:
  - Fraud hotline complaints
  - Claims data mining
  - Patterns identified through provider audits, civil false claims cases, and law enforcement investigations.
  - Allegations are considered to be credible when they have indicia of reliability.
- *Provided that* CMS or the Medicare contractor has consulted with the OIG, and, as appropriate, the Department of Justice ("DOJ"), and determined that a credible allegation of fraud exists.

- CMS, in consultation with the OIG, and the DOJ, as appropriate, has discretion as to whether prior notice of the payment suspension is appropriate.
- Provider afforded opportunity to submit rebuttal.
- Suspension of payment may be until resolution of the investigation (legal action is terminated by settlement, judgment, or dismissal or when the case is closed because of insufficient evidence)
  - *Unless* payment suspension has been in effect for 18 months and investigation is continuing → good cause not to continue suspension, except that CMS may extend beyond 18 months if:
    - OIG is considering case for administrative action (or administrative action is pending), OR
    - DOJ submits written request to CMS for continuing suspension of payments.

- The State Medicaid agency must also suspend all Medicaid payments to a provider after the agency determines there is a credible allegation of fraud for which an investigation is pending under the Medicaid program & notify the Medicaid Fraud Control Unit
  - Lower standard than current regulation which requires "*reliable information that fraud or willful misrepresentation exists*."
  - May suspend payments without first notifying the provider of its intention to suspend such payments. Notice only required:
    - To be provided 5 days after payment suspension, however, law enforcement may request delay in notice not to exceed 90 days
    - To set forth general allegations regarding suspension, not specific information concerning ongoing investigation
  - Provider may request, and must be granted, administrative review where State law so requires.

- In 2011, the Federal government won or negotiated approximately **$4.1 billion** in health care fraud judgments and settlements.
  - Department of Justice (DOJ) opened 1,110 new criminal health care fraud investigations involving 2,561 potential defendants.
  - Office of Inspector General (OIG) excluded 2,662 individuals and entities, including exclusions based upon:
    - criminal convictions for crimes related to Medicare and Medicaid (1,015)
    - Criminal convictions for crimes related to other health care programs (233)
    - patient abuse or neglect (206)
    - result of licensure revocations (897)

- In January 2011, Senior Care Group, Inc. agreed to pay $953,375 to settle allegations of fraud in two SNFs as a result of billing for unnecessary services.
  - Rehabilitation contractor pressured employees to maximize billings subsequently submitted to Medicare by Senior.
  - Included OT for Alzheimer's patients who could not expect to return to workforce.
- In April 2011, Genesis Rehabilitation Services agreed to pay $1.5 million to resolve allegations of submitting claims for services by unlicensed speech therapist.
  - Between October 2006 and June 2010 GRS allegedly employed ST who provided forged licenses and documentation to GRS.
  - GRS failed to verify.
  - Claims submitted were improper as performed by unlicensed individual.

- In January 2010, five nursing homes operated by Cathedral Rock pled guilty to felony health care fraud related to failure to provide adequate care to Medicare/Medicaid residents.
  - Majority owner entered into a criminal deferred prosecution agreement for 2 years.
  - $1 million in criminal fines & penalties, as well as $628,000 to resolve civil FCA allegations that they submitted false and fraudulent claims to Medicare / Medicaid.
  - Allegations of insufficient staffing levels; residents not receiving medication as prescribed; falsified medical records (i.e., "charting party" occurred to fill in medical records so that it appeared that all medication had been properly given, regardless of whether the medication was actually given or not); and submission of fraudulent claims to Medicare / Medicaid for services that were not provided / were worthless.
- In May 2010, Good Samaritan, a corporation which operates 230 nursing home facilities in virtually every state, agreed to pay $480,137 to resolve allegations that the corporation employed an excluded RN.
  - As a result, Good Samaritan was required to do a compliance review and certification during which the corporation uncovered six additional excluded employees working in other facilities, for which it paid an additional $200,000.

- In November 2009, Omnicare, Inc., the nation's largest nursing home pharmacy, agreed to pay $98 million, plus interest, to resolve FCA allegations that Omnicare submitted false claims to federal health care programs as a result of:
  - Providing consultant pharmacist services to nursing homes at below-cost / below FMV prices as a kickback to induce nursing homes to use Omnicare's dispensing pharmacist services and purchase drugs from Omnicare;
  - Soliciting and receiving $8 million in kickbacks from defendant IVAX Pharmaceuticals, Inc. in exchange for Omnicare's agreement to purchase $50 million in drugs from IVAX;
  - Paying a multi-million dollar kickback, disguised as the purchase amount for a business, to defendants Mariner Health Care, Inc. and SavaSeniorCare Administrative Services, LLC in exchange for agreements by Mariner and Sava to continue using Omnicare's pharmacy services for 15 years; and
  - Soliciting and receiving millions of dollars in kickbacks from defendant Johnson & Johnson in exchange for purchasing and recommending the drug Risperdal for use by patients in facilities served by Omnicare.
  - IVAX also agreed to pay $14 million to resolve liability for its role in this scheme.

- In 2012, OIG has identified the following focus 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
  - Safety and Quality of Post-Acute Care for Medicare beneficiaries (New)
  - NFs compliance with assessment and care planning requirements for residents receiving atypical antipsychotic drugs
  - Oversight and enforcement against poorly performing NFs
  - Hospitalizations of residents
  - Nursing homes' emergency plans and emergency preparedness deficiencies cited by State surveyors
  - Medicare Part B Services During Non-Part A Nursing Home Stays (New)
  - Implementation of Nursing Home Compliance Plans in accordance with OIG Guidelines (New)

- Effective March 25, 2011, *newly enrolling providers* will be categorized into one of three screening levels, based upon risk to the Medicare / Medicaid programs:
  - Limited
  - Moderate
  - High
- Effective March 23, 2012, *currently enrolled providers* will be subject to the same screening requirements in order to maintain enrollment (unless revalidating enrollment, then treated as new provider for purposes of screening requirements)

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- SNFs have been designated by CMS as "limited risk"
- Screenings for "limited risk" providers by Medicare contractors will include:
  - Verification that provider meets all applicable Federal regulations and State requirements
  - License verifications, including licensure verifications across State lines for providers that obtain or maintain Medicare billing privileges as a result of State licensure
  - Database checks on a pre- and post-enrollment basis to ensure that providers continue to meet the enrollment criteria for their provider-type (i.e., SSN/TIN; OIG exclusion; death of owner, delegated official, or supervising physician)
- Screenings for "limited risk" Medicaid-only providers by Medicaid contractors are the same, however, State Medicaid agency is given discretion to independently designate risk levels to Medicaid-only providers

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- PPACA mandates that state Medicaid agencies must exclude any individual or entity from participating in Medicaid
  - If such individual or entity is terminated from Medicare or another state Medicaid program "for cause" which may include fraud, integrity or quality issues (does not include voluntary termination, unless taken to avoid sanction) on or after January 1, 2011
    - Only after exhaustion of all available appeal rights (or timeline for appeal has expired)
    - CMS may also terminate from Medicare upon termination from any state Medicaid program
  - If such individual or entity owns, controls or manages an entity that (or if such entity is owned, controlled or managed by an individual or entity that):
    - Has unpaid overpayments
    - Is suspended, excluded or terminated from participation in Medicaid
    - Is affiliated with an entity or individual that has been suspended, excluded or terminated from participation in Medicaid
- Facilities must regularly check the online database for the list of providers and employees excluded from participation in the federal health programs and maintain records of all searches.
  - OIG Exclusion List - http://exclusions.oig.hhs.gov/
  - NJ Exclusion List - http://nj.gov/njomig/disqualified/

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- As of June 29, 2010, the New Jersey Office of the Medicaid Inspector General was transferred to the Office of the State Comptroller – Medicaid Fraud Division.
- MFD is comprised of approximately 49 full-time employees (including auditors, claim reviewers, investigators, physician specialists and nurses) → dedicated to fight fraud and abuse in the Medicaid program.
- Fiscal Integrity Unit consists of four sub-units:
  - Audit – independently conducts audits and oversees state-contracted auditors
  - Data Mining – reviews anomalous claim reimbursement behavior of providers (submits findings to audit or investigation)
  - Recovery & Exclusions – recovers overpayments and penalties identified by auditors and investigators
  - Third-Party Liability – recovers reimbursement from private insurers where services were inappropriately reimbursed by Medicaid (as payor of last resort)
- Investigative Unit investigates providers and recipients
- Regulatory Unit provides administrative, investigative and rule-making support to other MFD Unit; negotiate and monitor corporate integrity programs; review Medicaid regulations; and issue notices to the provider community.

- In 2012, MFD has identified the following focus areas for review:
  - Verifying that NFs have appropriately billed Medicare prior to Medicaid and if not, recover the Medicaid payment.
  - Pursuing referrals from outside auditors on clinical or financial audits where auditors' work indicates fraud, waste or abuse may have occurred.
  - Implementation of Recovery Audit Contractor (RAC) for fee-for-service and managed care providers by providing guidance as to types of audits to be conducted and follow up.

- PPACA mandates Medicaid recovery audit contractors (RACs) programs to identify & recover overpayments. States must:
  - Contract with RACs on a contingency basis (only from amounts recovered)
    - RACs only paid upon collecting overpayments (or as otherwise designated by the state for identifying underpayments)
    - RACs generally identify improper payments based upon non-covered services, medical necessity, incorrect coding and duplicate services
    - RACs do not replace any existing State program integrity or audit initiatives
    - Proposed regulations provide that RACs must report fraud / criminal activity to appropriate law enforcement officials
    - Risk of whistleblower actions under FCA by RAC contractors
  - Provide appeal process for adverse Medicaid RAC determinations

- PPACA included the enactment of the Elder Justice Act which establishes a federal elder justice program to prevent, detect, treat, intervene in and prosecute elder abuse, neglect, and exploitation and improve long term care, including:
  - Establishment of the:
    - Elder Justice Coordinating Council
    - Advisory Board on Elder Abuse, Neglect and Exploitation
    - National Training Institute for Federal and State surveyors
  - Authorization of federal grants for:
    - stationary and mobile forensic centers,
    - adult protective services
    - improved staffing and staff training
    - long-term care ombudsman program
    - offsetting costs of electronic health record technology for eligible facilities
  - Authorization of HHS study concerning federal nurse aid registry
  - **Mandatory reporting of suspected elder abuse crimes and employee protection from retaliation for such reporting**.

- Federal law requires reporting of incidents occurring within facility to administrator and then report in accordance with state law.
- Now, each individual who is an owner, operator, employee, manager, agent or contractor (a "Covered Individual") of a long-term care facility that receives at least $10,000 in annual federal funding under the Social Security Act must report ***any reasonable suspicion of a crime*** against any individual who is a resident of, or is receiving care from, the facility.
- The mandatory report must be made to the Department of Health and Senior Services on behalf of the Secretary of HHS and at least one local law enforcement authority:
  - If the suspected crime results in serious bodily injury, the mandatory report must be made **immediately and in no event later than 2 hours after forming the suspicion**.
  - If the suspected crime does not result in serious bodily injury, the report must be made **no later than 24 hours after forming the suspicion**.

- For the purposes of the Elder Justice Act reporting requirements:
  - Crime is defined by the law of the applicable political subdivision
  - "serious bodily injury" is defined as an injury:
    - involving extreme physical pain
    - involving substantial risk of death
    - involving protracted loss or impairment of the function of a bodily member, organ, or mental faculty
    - requiring medical intervention such as surgery, hospitalization, or physical rehabilitation

- The law does not specify the necessary mechanism for submitting the report to DHSS and law enforcement, nor does it specify the required contents of the report.
- Given the strict time limits for such mandatory reporting, such reports should likely be in the form of a facsimile, including, at a minimum, a description of the suspected crime, names of all covered individuals required to report and confirmation of the report to law enforcement.

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- Requires annual notification to all Covered individuals of the obligation to comply with the mandatory reporting requirements.
- Requires posting a sign (in a form to be, but not yet, specified by the Secretary) notifying employees that the facility is prohibited from:
  - discharging, demoting, suspending, threatening, harassing, or denying a promotion or other employment-related benefit to an employee, or in any other manner discriminating against an employee in the terms and conditions of employment because of lawful acts done by the employee; or
  - filing a complaint or a report against a nurse or other employee with the appropriate State professional disciplinary agency because of lawful acts done by the nurse or employee
  - employee notification must also include a statement that an employee may file a complaint with the Secretary of HHS against a long-term care facility that violates the provisions of the Elder Justice Act and information with respect to the manner of filing such a complaint

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- Penalties for failing to report:
  - Civil monetary penalties up to $200,000 (or $300,000 if the violation is deemed to exacerbate the harm to the victim)
  - Potential exclusion from participation in all Federal health care programs
  - Potential ineligibility for Federal funds in the event that a long-term care facility employs an excluded individual during the period of such exclusion.
- Penalties for retaliation:
  - Civil monetary penalties up to $200,000
  - Possible exclusion from participation in Federal health care programs for a period of 2 years.

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- Steps towards compliance:
  - Determine whether facility receives at least $10,000 in federal funding
  - If applicable, review and revise existing policies, procedures and compliance programs to reflect new mandatory reporting requirements and consider whether to designate a single individual within the facility to be responsible for such reporting
  - Educate all Covered Individuals concerning their mandatory reporting obligation (including consequences of "excluded individual" status for failure to report) and establish a plan for implementing annual notification to all such Covered Individuals
  - Post (in a conspicuous location) a Retaliation Disclosure to Employees
  - Look for future guidance and/or regulations from HHS on these reporting requirements / content of the mandated Retaliation Disclosure to Employees

- Effective March 25, 2011, PPACA mandates new disclosure requirements for ownership or control interest → all Medicaid providers must disclose, in addition to the prior requirements with respect to ownership / control interest (i.e., name & address of any individual or entity with an ownership or control interest in the provider, as well as related parties):
  - DOB or SSN OR TIN of all individuals / entities with an ownership or control interest in the disclosing entity (or in any subcontractor in which the disclosing entity has a 5% or more interest), as well as the primary & all business addresses of corporate entities
  - Name, address, DOB and SSN of any managing employee of the disclosing entity.

- *Disclosures* are required:
  - Upon submission of the provider application
  - Upon execution of the provider agreement
  - Upon request of the Medicaid agency during the re-validation of enrollment process
  - Within 35 days after any change in ownership

- PPACA also mandates NFs/SNFs to disclose additional information on ownership, including a description of the governing body and organizational structure and information regarding additional disclosable parties
- Pursuant to regulations proposed by CMS on May 6, 2011 (not yet final), an NF/SNF would be required to report upon enrollment and within 30 days of any change, the identity of and information on all of the following:
  - Each member of the governing body of the facility (including name, title, & period of service for each member)
  - Each person or entity who is an officer, director, member, partner, trustee, or managing employee of the facility (including name, title, & period of service of each such person or entity)
  - Each additional disclosable party of the facility (including the organizational structure of each additional disclosable party of the facility & a description of the relationship of each such additional disclosable party to the facility and to one another)
- Finally, NFs/SNFs would also be required to certify as a condition of participation and payment that all of the above is, to the best of the facility's knowledge, accurate and current

- For the purposes of these reporting requirements, the following definitions apply:
  - "**Additional disclosable party**" includes any person or entity who –
    - Exercises operational, financial, or managerial control over the facility or a part thereof, or provides policies / procedures for any of the operations of the facility, or provides financial / cash management services to the facility;
    - Leases or subleases real property to the facility, or owns a whole or part interest equal to or exceeding 5% of the total value of such real property; or
    - Provides management / administrative services, management / clinical consulting services, or accounting / financial services to the facility.
  - "**Managing employee**" includes any individual, including a general manager, business manager, administrator, director, or consultant, who directly or indirectly manages, advises, or supervises any element of the practices, finances, or operations of the facility.

- For the purposes of these reporting requirements, the following definitions apply (cont.):
  - "**Organizational structure**" means, in the case of a:
    - *Corporation* – the officers, directors, & shareholders of the corporation who have an ownership interest in the corporation which is equal to or exceeds 5 percent
    - *Limited liability company* ("LLC") – the members & managers of the LLC including, as applicable, what percentage each member & manager has of the ownership interest in the LLC
    - *General partnership* – the partners of the general partnership
    - *Limited partnership* ("LP") – the general partners & any limited partners of the LP who have an ownership interest in the LP which is equal to or exceeds 10 percent
    - *Trust* – the trustees of the trust
    - *Individual* – contact information for the individual

- 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)

- 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

- 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

OIG Guidance
For Nursing Facilities
Issued September 30, 2008

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

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- 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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- "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."

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

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

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

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- 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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- 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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- 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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- 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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- 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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- 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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- 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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- 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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- 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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- 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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- 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.

- 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

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

- 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.

- 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;

- 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.

- 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.

- 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

- 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

- 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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