Establishing Healthcare Compliance Programs as Mandated by the PPACA
Implementing Effective Reporting, Exclusion Screening, and Formal Risk Assessment Processes

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Establishing Health Care Compliance Programs

November 14th, 2012

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Healthcare Compliance Programs

Historically HCP’s were:

“favored”
“recommended”
“helpful”
“valuable”

But generally not required for healthcare providers

In 2010 that changed!

PPACA will now mandate that Medicare providers and suppliers maintain written compliance programs.

Mandatory Compliance Programs

Under PPACA most healthcare providers and suppliers will be obligated to implement a compliance and ethics program that is effective in preventing and detecting criminal, civil and administrative violations.

*See Sec.’s 6102 and 6401.*
Mandatory Compliance Programs (cont.)

Two Categories under PPACA

1. Skilled Nursing Facilities and Nursing Facilities (as defined in Sections 1819(a) and 1919(a) of the Social Security Act)
   • See Sec. 6102

2. All other providers/suppliers (as a condition of enrollment in Medicare)
   • See Sec. 6401.
Required 8 Components of Nursing Facility Compliance Programs

• Compliance standards “that are reasonably capable of reducing the prospect” of criminal, civil, and administrative violations;

• Assignment of overall compliance program oversight to “high-level personnel” with “sufficient resources and authority” to assure compliance;

• Exercise of “due care” not to delegate “substantial discretionary authority” to individuals who have a “propensity to engage in criminal, civil, or administrative violations”;

• Effective communication of compliance standards to all employees/agents through training programs or publications;
Required 8 Components of Nursing Facility Compliance Programs (cont.)

- Adoption of monitoring and auditing systems designed to detect compliance violations and a mechanism for employees/agents to report violations without fear of retribution;

- Consistent enforcement of appropriate disciplinary mechanisms;

- Reasonable responses to reported/detected offenses, including steps to prevent further similar offenses; and

- Periodic reassessment of the compliance program to identify necessary modifications.
  - See Sec. 6102(b)(4).
Nursing Facility Implementation Timeline

- March 23, 2012 – HHS/OIG were to promulgate regulations for an “effective compliance program” for nursing facilities.
  - Deadline was not met.

- However, 2012 OIG Work Plan notes that “we will review…nursing homes’ implementation of compliance plans as part of their day-to-day operations and whether the plans contain elements identified in OIG’s compliance program guidance…”
  - See 2012 OIG Work Plan, pg. I-10

- 2012 Work Plan directs facilities to currently published compliance guidance for nursing facilities.
Nursing Facility Implementation Timeline (cont.)

March 23, 2013
Deadline for nursing facilities to implement a compliance and ethics program that meets PPACA’s criteria
Mandatory Compliance Programs for Other Healthcare Providers

- PPACA sets no specific implementation deadline for other providers.

- Timeline for implementation and date of implementation is to be determined by HHS/OIG for providers and suppliers within a “particular industry” or “category.”
  - See Sec. 6401(a)(7)(c).

- Establishment of core compliance program elements and implementation deadlines is at the discretion of HHS/OIG.
  - See Sec. 6401(a)(7).

- HHS is to consider extent to which adoption of compliance programs is widespread in a “particular industry sector or provider or supplier category.”
  - Id.
Mandatory Compliance Programs for Other Healthcare Providers (cont.)

• To date, HHS/OIG has not published “core elements” or an implementation deadline.

• HHS/OIG has indicated that it intends to use the 7 elements described in Ch. 8 of the U.S. Sentencing Guidelines (“USSG”) as the basis for the “core elements”.

• HHS/OIG believe the USSG elements “instill a commitment to prevent, detect and correct inappropriate behavior and ensure compliance with all applicable federal laws, regulations and requirements.”
  • Id.

• Statute contemplates that core elements may vary by “particular industry sector or category” of provider or supplier.
  • See Sec. 6401(a)(7)(A) and (B).
Primary Sources of Guidance on Developing Compliance Programs

- OIG Compliance Program Guidance
- U.S. Sentencing Guidelines
- “HEAT” Compliance Guidance
Beginning in 1998, the OIG developed a series of voluntary Compliance Program Guidance documents directed at various categories of the health care industry to encourage the development and use of internal controls to monitor adherence to applicable statutes, regulations, and program requirements.
OIG Compliance Program Guidance (cont.)

• **Nursing Facilities**
  - Original Compliance Program Guidance
    • 65 Fed. Reg. 14289; March 16, 2000
  - Supplemental Guidance
    • 73 Fed. Reg. 56832; September 30, 2008

• **Hospitals**
  - Original Compliance Program Guidance
    • 63 Fed. Reg. 8987; February 23, 1998
  - Supplemental Guidance
    • 70 Fed. Reg. 4858; January 31, 2005

• **Individual and Small Group Physician Practices**
  • 65 FR 59434; October 5, 2000.

• **Pharmaceutical Manufacturers**
  • 68 FR 23731; May 5, 2003.
OIG Compliance Program Guidance (cont.)

- **Ambulance Suppliers**

- **Medicare+Choice Organizations**
  - 64 FR 61893; November 15, 1999.

- **Hospices**
  - 64 FR 54031; October 5, 1999.

- **DME, etc.**
  - 64 FR 36368; July 6, 1999.
OIG Compliance Program Guidance (cont.)

- **Third Party Medical Billing Companies**
  - 63 FR 70138; December 18, 1998.

- **Clinical Laboratories**
  - 63 FR 45076; August 24, 1998.

- **Home Health Agencies**
  - 63 FR 42410; August 7, 1998.
Additional OIG Compliance Guidance

- Roadmap for New Physicians
- Compliance Resources for Healthcare Boards

See https://oig.hhs.gov/compliance/101/index.asp
U.S. Sentencing Guidelines

- Chapter 8 applies to sentencing of organizations.
- Two factors may mitigate ultimate punishment:
  - Existence of an effective compliance and ethics program; and
  - Self reporting cooperation and acceptance of responsibility


“These guidelines offer incentives to organization to reduce and ultimately eliminate criminal conduct through and effective compliance and ethics program.”

Id.
U.S. Sentencing Guidelines (cont.)

- Two basic requirements of an effective compliance and ethics program:
  - Exercise of due diligence to prevent and detect criminal conduct; and
  - Promotion of an organizational culture that encourages ethical conduct and a commitment to compliance with the law

U.S. Sentencing Guidelines (cont.)

- Basic requirements are fulfilled through seven (7) concepts:

  1. Standards and procedures to prevent and detect criminal conduct;

  2. A governing authority that is knowledgeable about the program and exercises reasonable oversight; specific high-level personnel are assigned overall responsibility for program; specific individuals who report to governing body are delegated day-to-day operational responsibility, and adequate resources are devoted.
U.S. Sentencing Guidelines (cont.)

3. Reasonable efforts not to include within personnel with substantial authority individuals whom organization knows or reasonably should know have engaged in illegal activities;

4. Reasonable steps to periodically communicate the standards and procedures to the governing body, high-level personnel, persons with substantial authority, other employees and agents through effective training;

5. Reasonable steps to ensure program is followed through monitoring, auditing and evaluation periodically the effectiveness of the program and implementation of system whereby employees and agents may report violations or seek guidance without fear of retaliation;
U.S. Sentencing Guidelines (cont.)

6. Consistent enforcement of the program through appropriate incentives and disciplinary measures; and

7. Reasonable steps to respond appropriately after criminal conduct is detected and to prevent further similar conduct, including modifying the program as necessary.
U.S. Sentencing Guidelines (cont.)

• Formality and scope of actions depend on the size of the organization
  • **Large Organizations** – expected to devote more formal operations and greater resources to requirements and to encourage small organizations having relationships to implement programs
  • **Small Organizations** – expected to demonstrate same level of commitment to compliance as large organizations, but with less formality and fewer resources
“HEAT” Initiative

In May 2009, DOJ and HHS announced the creation of the “Health Care Fraud Prevention and Enforcement Action Team” (“HEAT”).
Mission of HEAT

• To gather resources across the government to help prevent waste, fraud and abuse in the Medicare and Medicaid programs, and crack down on the fraud perpetrators who are abusing the system and costing us all billions of dollars.

• To reduce skyrocketing health care costs and improve the quality of care by ridding the system of perpetrators who are preying on Medicare and Medicaid beneficiaries.
Mission of HEAT (cont.)

- To highlight best practices by providers and public sector employees who are dedicated to ending waste, fraud and abuse in Medicare

- To build upon existing partnerships between DOJ and HHS such as Medicare Fraud Strike Force to reduce fraud and recover taxpayer dollars
HEAT Compliance Guidance

As part of HEAT’s Provider Compliance Training Initiative, the OIG website has free videos and audio podcasts (averaging about four minutes each) which cover major health care fraud and abuse laws, the basics of health care compliance programs, and what to do when a compliance issue arises.

https://oig.hhs.gov/compliance/provider-compliance-training/index.asp#materials
• Reasons Clients Must Take Mandatory Compliance Program Seriously
Enhanced Enforcement Environment

Under PPACA

- 60 day rule
  - Sec. 6402(a)
- Elimination of bar against qui tam actions based on “public disclosure”
  - Sec. 1303(j)(2)
- Anti-Kickback Violations as False Claims
  - Sec. 6402(f)(1)
- Anti-Kickback Statute Intent Standard modified
  - Sec. 6402(f)(2)
- Expanded Civil Monetary Penalties
  - Sec. 6408
- Stark Self-Disclosure Protocol
  - Sec. 6409
Enhanced Enforcement Environment (cont.)

• Fiscal Year 2011
  • Record breaking recoveries from health care fraud enforcement of almost $4.1 billion - 1,110 new criminal health care fraud investigations, involving 2,561 potential defendants
  • 1,873 health care fraud criminal investigations pending, involving 3,118 potential defendants
  • 743 defendants convicted of health care fraud related crimes
  • 977 new civil health care fraud investigations
  • 1,069 civil health care fraud investigations pending
  • 2,662 excluded individuals and entities

Executive Summary, The Department of Health and Human Service and The Department of Justice Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2011
Other Reasons Why Clients Should Take Mandatory Compliance Programs Seriously

• They are mandates of the law

• Failure to comply can result in termination of Medicare/Medicaid participation/certification

• They can effectively avoid substantial liability – especially in light of the enhanced enforcement environment in the health care industry
Other Reasons Why Clients Should Take Mandatory Compliance Programs Seriously (cont.)

• If a violation occurs an effective compliance plan could possibly reduce fines and penalties

• The existence of a compliance plan can assist in overcoming a charge of “reckless disregard or deliberate ignorance”
Establishing Healthcare Compliance Programs as Mandated by the PPACA

Compliance Program
Essential Elements

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Elements of an Effective Compliance Program

Chapter 8 of the U.S. Federal Sentencing Guidelines Manual

OIG Compliance Guidance
7 Essential Elements

- Written policies and procedures
- Compliance Officer
- Training and education
- Internal monitoring and auditing
- Open lines of communication
- Investigation of violations and corrective action initiatives
- Appropriate disciplinary measures
#1 Establish Written Standards and Procedures to Prevent and Detect Criminal Conduct

- Identify risk areas
- Develop written policies and procedures to address risk areas
- Update clinical forms periodically to ensure clear and complete documentation of patient care and medical necessity
- Communicate with employees regarding the establishment and/or update of policies and procedures
- Retention of compliance, business, and medical records
Coding and Billing

Risk areas to watch out for include:

- Billing for items or services not rendered or not provided as claimed
- Submitting claims for equipment, medical supplies, and services that are not reasonable and necessary
- Double billing resulting in duplicate payment
- Billing for non-covered services as if they were covered
- Knowing misuse of provider ID numbers, which results in improper billing
- Unbundling
- Failure to properly use coding modifiers
- Upcoding the level of service provided
Reasonable and Necessary Services

Medicare will only pay for services that meet its definition of reasonable and necessary “for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”

The provider should be able to provide documentation, such as patient medical records and physician orders, to support the appropriateness of a service provided by the provider.
Documentation

Necessary to determine the appropriate medical treatment for the patient and as the basis for coding and billing determinations

• Medical records must be complete and legible
• Each patient encounter must include: documentation of the reason for the encounter; any relevant history; physician exam findings; prior diagnostic test results; assessment, clinical impression, or diagnosis; plan of care; and date and legible identity of the observer
• Rationale for ordering diagnostic and other ancillary services must be documented or easily inferred
• Identify appropriate health risk factors involving the patient
• CPT and ICD-9 codes must be supported by documentation and the medical record
Improper Inducements, Kickbacks, and Self-Referrals

- Policies and procedure should encourage compliance with the Stark Law and Anti-Kickback Statute

Risk areas include:
- Joint ventures with entities that supply goods or services to the provider or its patients
- Consulting contracts or medical directorships
- Office and equipment leases between the provider and entities to which its physicians refer
- Soliciting, accepting, or offering any gift or gratuity of more than nominal value to or from those who may benefit from a physician or the provider’s referral of federal healthcare program business
#2 – Designate a Compliance Officer

- Perform day-to-day operational responsibilities
- Prepare and update written policies and procedures
- Conduct periodic audits
- Respond to billing questions
- Develop and coordinate a training program for employees regarding the compliance program
- Ensure that each employee is not excluded or debarred from participation in federal healthcare programs
- Investigate reports or allegations of unethical or improper business practices, and monitor subsequent corrective action and/or compliance
#3 – Conducting Appropriate Training and Education

- Determine who needs training, what types of training to use (in-person, self-study, etc.), and when and how often to train
- Train employees about the compliance program and specific risk areas
- Training about the compliance program should occur during orientation or beginning of employment, and annually thereafter
- Compliance should be made a condition of continued employment
#4 – Auditing and Monitoring

Ongoing evaluation of the compliance program and its effectiveness is vital to its success

- Periodic review of the written policies and procedures to determine if they are current and complete
- Periodic audit of claims submissions to ensure compliance with coding, billing, and documentation requirements
- Appropriate response when an audit identifies a problem
  - Action should be taken as soon as possible after the problem is identified
  - Response will depend upon the situation – repayment, consultation with a coding/billing expert, etc.
#5 – Developing Open Lines of Communication

Need a clear open door policy between physicians and compliance personnel and employees

- Require employees to report conduct that a reasonable person would believe to be wrong or fraudulent
  - Failure to report is considered a violation of the compliance program
- Create a user-friendly process for reporting
- Develop a simple procedure to process received reports
- Allow for employees to report allegations anonymously or confidentially
- Emphasize there will be no retribution or retaliation against employees who make good faith reports
The Compliance Officer is responsible for investigating the allegations to determine whether there has been a violation of applicable law or compliance program requirements.

- If a violation did occur, the provider must respond and document its investigation and response.
- If the violation involved an individual, determine whether to retrain, discipline, or terminate employment.
- Provider should make any necessary modifications to the compliance program to prevent similar violations in the future.
#7 – Enforcing Disciplinary Standards

Consequences of non-compliance should be enforced consistently

- Disciplinary standards should be flexible enough to account for mitigating or aggravating circumstances
- Those who fail to detect or report violations of the compliance program could be subject to discipline
- Full range of disciplinary actions
Other Requirements

• Use reasonable efforts not to employ any individual with substantial authority whom the provider knows, or should know, has engaged in illegal activities or other unethical misconduct

• Written policies and procedures should not be a “wish list” of behaviors – they should reflect actual practice

• Once a provider has developed a compliance program, remember that it is only effective if it is actually used
General Guidance

Exercise due diligence to prevent and detect criminal conduct

Promote an organizational culture that encourages ethical conduct and a commitment to compliance with the law
Additional Information

The Official Web Site for the Office of the Inspector General
http://oig.hhs.gov/

Link to OIG Compliance Guidance
https://oig.hhs.gov/compliance/compliance-guidance/index.asp

Establishing Healthcare Compliance Programs as Mandated by PPACA

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November 14, 2012
60 Day Refund Rule

PPACA Section 6402; 42 USC 1320a-7k(d)

- Must report and return known overpayments within 60 days of the date identified, or else a False Claims Act violation.
- Effective March 23, 2010
- Proposed rule issued Feb 13, 2012
60 Day Refund Rule

1. What is an “overpayment”?
2. When is an overpayment “identified”?
3. When does the clock start running?
4. What to do regarding potential overpayments?
5. What should an overpayment policy look like?
60 Day Refund Rule

When is an overpayment “identified”?

- An overpayment is “identified” when a person has actual knowledge or act in reckless disregard or deliberate ignorance of the overpayment.
60 Day Refund Rule

When does the clock start running?

- The 60 day clock does not start running until after the provider has an opportunity to undertake a “reasonable inquiry” into the basis of the alleged overpayment.
- But you must conduct the inquiry with due diligence and all deliberate speed.
- CMS also stated that when a government agency informs a provider or supplier of a potential overpayment, the provider or supplier has an obligation to accept the finding or make a reasonable inquiry.
60 Day Refund Rule

What to do regarding potential overpayments?

- Establish policy and process
- Use a work plan
- Consult with legal counsel
- Perform investigation
- Document review, interviews, analysis
- Quantification of overpayment (extrapolation vs 100% review). Consider payor sources
- Conclusion and recommended action
- Report and refund
- Corrective action to prevent recurrence
60 Day Refund Rule

What to do regarding potential overpayments?

- 10 year look back period?!?!?
- New process to be specified in Ch. 4 of the Medicare Financial Management Manual. CMS expects to create a standard form.
- Contractor forms; State Medicaid self-disclosure protocols; cover letter for context; statistician report
60 Day Refund Rule

Creating a P&P on 60 Day Refund Rule

- Don’t create a policy that requires an unworkable bureaucracy or over-complicated process. It should be nimble, clear, and easy to complete in a timely manner.

- Do create a policy that allows for flexibility when information changes/develops during the investigation.

- Do create a policy that demonstrates the effectiveness of the organization’s compliance plan.
60 Day Refund Rule

Creating a P&P on 60 Day Refund Rule

- Do include in the policy any necessary internal approvals which are required for processing of the refund, and build in time for securing these approvals.

- Don’t create a policy that conflicts with the organization’s internal accounting policies without first getting input from auditors and legal counsel.

- Do implement robust training and education around the policy, how to spot overpayments, the requirements for internal (or external) reporting, and the organization’s commitment against retaliation for whistleblowers and reporters.
Employee Screening

- **USSG Element:**
  
  The organization shall use reasonable efforts not to include within the substantial authority personnel of the organization any individual whom the organization knew, or should have known through the exercise of due diligence, has engaged in illegal activities or other conduct inconsistent with an effective compliance and ethics program.
Employee Screening

- Upon hire
- During continued employment
- Periodic, regular reviews of exclusion lists
  - How frequently does OIG update the LEIE?
  - How frequently should a provider check the LEIE?
- Criminal background checks
  - State licensure rules; Medicaid rules
- Outsource vs. in-house
- [http://exclusions.oig.hhs.gov/](http://exclusions.oig.hhs.gov/)
Employee Screening

- **OIG LEIE:** [exclusions.oig.hhs.gov](http://exclusions.oig.hhs.gov)
  - OIG’s List of Excluded Individuals/Entities (LEIE) provides information to the health care industry, patients and the public regarding individuals and entities currently excluded from participation in Medicare, Medicaid and all other Federal health care programs. Individuals and entities who have been reinstated are removed from the LEIE.

- **GSA Excluded Parties System:** [www.epls.gov](http://www.epls.gov)
  - The Excluded Parties List System (EPLS) includes information regarding entities debarred, suspended, proposed for debarment, excluded or disqualified under the nonprocurement common rule, or otherwise declared ineligible from receiving Federal contracts, certain subcontracts, and certain Federal assistance and benefits.
Employee Screening

- If you have only a few names to search, consider using the Online Searchable Database. It allows you to search up to five names at one time and to verify identities using a Social Security number or date of birth.

- If you have a large group of individuals to search, consider downloading the entire list via the LEIE Downloadable Datafile to your computer and using a spreadsheet or database program to perform searches.

- Note: The Downloadable Datafile does not contain SSNs or EINs. Therefore, verification of specific individuals or businesses through the use of the SSN or EIN must be done via the Online Searchable Database.
Compliance Effectiveness Review

What is it?

- Compliance risk is further mitigated through internal review processes.
- Monitoring and auditing provide early identification of program or operational weaknesses and may substantially reduce exposure to government or whistleblower claims.
- One effective tool is the performance of regular, periodic compliance audits by internal or external auditors.
- In addition to evaluating the organization’s conformance with reimbursement or other regulatory rules, or the legality of its business arrangements, an effective compliance program periodically reviews whether the compliance program’s elements have been satisfied.
Compliance Effectiveness Review

- When do conduct it?
- What does it include?
- Document reviews/Interviews
- What to do with the results?