

HOLLAND & HART^{LLP}



Compliance Plans

Kelly S. McIntosh

July 20, 2017

Roadmap



- The importance of compliance and compliance programs
- Common compliance issues – know your risk areas!
- Guidance for drafting or updating your compliance plan
 - Elements of a compliance plan
 - Compliance is a process
- Measuring compliance program effectiveness
 - *“Measuring Compliance Program Effectiveness: A Resource Guide”* – OIG
 - *“Evaluation of Corporate Compliance Programs”* - DOJ

Preliminaries



- Written materials:
 - PowerPoint slides
 - OIG Compliance Program Guidance for Individual and Small Group Physician Practices (65 Fed. Reg. 59434; October 5, 2000)
 - OIG Guide
 - DOJ FAQ

- Presentation will be recorded and available for download at www.hhhealthlawblog.com

Preliminaries



- If you have questions, please submit them using chat line or e-mail me at ksmcintosh@hollandhart.com.
- If you experience technical problems during the program, please contact Luke Kelly at lskelly@hollandhart.com

Preliminaries



- This program offers an overview of legal considerations for compliance plans
- Not “one size fits all” - a compliance program needs to reflect your provider type, size and circumstances
- This program does not establish an attorney-client relationship
- This program does not constitute the giving of legal advice

Without Compliance



Risks



- Enforcement
 - False Claims Act (31 U.S.C. §§ 3729-3733)
 - Exclusion (42 U.S.C. § 1320a-7)
 - Civil Monetary Penalties Law (42 U.S.C. § 1320a-7a)
 - Criminal (18 U.S.C. § 287, 1001, 1035, 1347)
- Duty to self-report and make repayments
 - Medicare overpayments must be repaid 60 days after identify existence of overpayment, or by the date the corresponding cost report is due
- *Qui Tam* actions
- Audits

Risks



- Fines and Settlements
- Reputation Harm
- Operational Interruptions
- Lost Profits

Risks



- In 2016, the OIG reported:
 - More than \$3.3 billion in recovery
 - 765 criminal actions
 - 690 civil actions
 - 3,635 exclusions
- 2017 - over 40 new Corporate Integrity Agreements – so far



But...Do I Really Need a Plan?



Mandatory Compliance Plans – Affordable Care Act



- Section 6401 of the ACA requires compliance plans for providers across industry sectors and categories (as selected by HHS) as condition for Medicare/Medicaid/CHIP enrollment
- Section 6102 of the ACA requires that skilled nursing facilities (SNFs) adopt compliance plans by March 23, 2013.
- Implementing regulations have not been issued

Mandatory Compliance Plans – Affordable Care Act



- Future applicability?

- Be proactive – no need to wait for regulations to establish plan
 - **OIG guidance for compliance plans**
 - Hospitals
 - Home Health Agencies
 - Clinical Laboratories
 - Third-Party Billing Companies
 - Medicare+Choice Orgs
 - Nursing Facilities
 - Ambulance Suppliers
 - Pharmaceutical Manufacturers
 - DME, Prosthetics and Orthotics Suppliers

Mandatory Compliance Plans – Others



- Medicare Advantage (MA) managed care entities
- Prescription drug (Part D) plan entities



Other Reasons to Have a Compliance Program



- Public and organizational image - demonstrates commitment to “doing the right thing”
- Reduces risk of audit
- Minimizes requirement (or impact) of a CIA
- Mitigation factor
- Reduces threat of *Qui Tam* (whistleblower) actions
- Raises awareness throughout organization
- Encourages reporting

Other Reasons to Have a Compliance Program



- **Good Business**

- Increases efficiency of claims payments
- Reduces denied claims
- Improves documentation
- “Practicing preventative medicine” for your organization

Identifying Your Risks



- Your practice will have specific risks
 - Size, provider type
 - OIG compliance guidance is a good starting point for common risks based on type

- Examples:
 - Physician practice risk areas
 - Documentation
 - Billing and coding
 - Improper inducements

Identifying Your Risks



- Revisit risks
 - Each year is good rule of thumb
- Sources for new and timely risk considerations:
 - OIG Annual Work Plan
 - (<http://oig.hhs.gov/reports-and-publications/workplan/index.asp>)
 - RAC approved issues lists
 - State and federal reports
- Don't forget YOUR internal sources!
 - Complaints
 - Staff interviews
 - Audit reports

Your Compliance Plan



- Seven fundamental elements of a compliance program:
 1. Implementing compliance standards (policies, procedures and standards of conduct)
 2. Designating a compliance officer and/or committee
 3. Conducting training and education
 4. Developing open lines of communication
 5. Conducting internal monitoring and auditing
 6. Enforcing standards through well-publicized disciplinary guidelines
 7. Promptly and appropriately responding to detected issues, including corrective action

Your Compliance Plan



- From the Federal Sentencing Guidelines
 - Control sentencing of organizations in most Federal criminal violations
 - Credit for “effective programs to prevent and detect violations of law”
 - “Effectiveness” is key
- Interdependence of elements



Your Compliance Plan



- Commitment to all elements, even if implemented over time
- For physician practices, take a step-by-step approach to implementing a compliance program based on resources available – not all or nothing
- Participate in other organizations' programs

Standards, Policies and Procedures



- Code of Conduct
 - Separate from policies and procedures
 - Simple, short
 - Set forth the ethical attitude of the organization
 - Outline duties and goals
 - Post prominently and distribute

Policies, Procedures and Standards of Conduct



- Areas to cover (as applicable to your provider type):
 - Billing and Coding
 - Reasonable and necessary services
 - Documentation (medical records and claims forms)
 - Improper inducements, kickbacks and self-referrals
 - Employment/Labor Issues
 - Safety
 - EMTALA
 - Information Privacy and Security (HIPAA/HITECH/state)
 - Record Retention
 - Accreditation
 - Other Federal and State Laws

Policies, Procedures and Standards of Conduct



- Policies and procedures can also further detail functions of the compliance program:
 - Reporting mechanisms
 - Investigations

- Put in writing and maintain where staff can access

- Avoid overly complex language

- Include examples

Policies, Procedures and Standards of Conduct

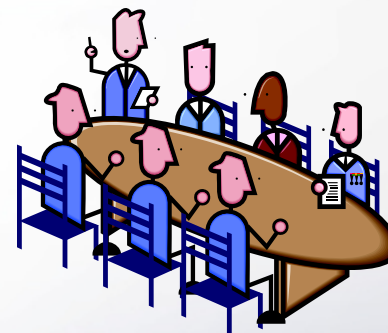


- Don't let these collect dust!
- Update as appropriate – at least review annually
- Identify who is responsible under each policy
- Educate staff and responsible parties on policies
- Distribute to staff and have them acknowledge receipt and review

Compliance Officer and/or Committee



- Providers of any type and size should designate a compliance officer/contact (or officers/contacts)
- For larger organizations, a compliance committee may also be appropriate
- Sub-committees
 - Audit
 - Enforcement



Compliance Officer and/or Committee



- Compliance officer duties:
 - Develop and update policies
 - Training
 - General – Preliminary and Periodically
 - Targeted – Specific topics and in response to issues
 - Ensure independent contractors are aware of compliance plan
 - Point person for complaints and investigations
 - Independence is important
 - Increases effectiveness
 - Promotes buy-in from staff

Training and Education



- Training
 - Who should receive training?
 - EVERYONE – including management and Board
 - Remember to consider outside and related parties like billing companies
 - Compliance officer and committees should also have ongoing training and education
 - General
 - Upon hire
 - Upon implementation of compliance program
 - Annually
 - Targeted – Specific topics and in response to issues
 - Maintain training logs

Training and Education



- Board and Senior Management Responsibilities
 - Responsible for compliance program
 - Can be held accountable for non-compliance *whether aware or not*
 - If in a position to prevent and correct issues but fail to do so, can be held liable, even criminally
 - The OIG will hold senior officials liable for fraud
 - CMS guidelines on Governing Body and Senior Management within Medicare Manuals for certain provider types
 - Hospital
 - ASC

Reporting and Communication



- Mechanisms for reporting
 - Internal vs. external
 - Non-retaliation policy
 - Confidentiality and anonymity
 - Exit interviews

Reporting and Communication



- Developing open lines of communication:
 - Access to compliance officer
 - Use “reasonable person” standard – require reporting for conduct a reasonable person would believe erroneous or fraudulent
 - User-friendly process
 - Drop box
 - Phone line
 - Email/website



Reporting and Communication



■ Investigations

- Define process through policies
- Attorney-client privilege considerations
- Interviews and information collection
- Confidentiality
- Reporting to leadership



Monitoring and Auditing



- Define the difference between monitoring and auditing
- Monitoring:
 - Ongoing “self-review” of areas to assess and assure processes and systems are compliant.
 - Not usually independent
- Auditing:
 - Objective (and often independent) look at an area for the purposes of reporting factual results

Monitoring and Auditing



- Baseline audit – know where you are starting from
 - Look to a specific period of time (e.g. 3 months after initial training and program implementation)
- Concurrent vs. retrospective
- Internal vs. external
- Sharing results throughout organization

Monitoring and Auditing



- Examples of items to monitor:
 - Excluded persons list (<http://exclusions.oig.hhs.gov/>)
 - Physician relationships

Monitoring and Auditing



- Examples of items to audit:
 - Standards and procedures (the compliance program!)
 - For each of the elements ask:
 - Have you established a structure to comply with the requirement?
Is the content sufficient?
 - Do you properly implement the requirement?
 - Do you measure the program effectiveness? What internal controls, indicators, or outcomes do you have to give assurance that the structure/processes implemented are working?
 - Claims (coding, documentation, medical necessity)

Monitoring and Auditing



- **OIG recommendations for auditing:**
 - Annual review
 - 5 or records per Federal payor
 - 5-10 records per physician
- **Larger sample size = more confidence in results**



Enforcement through Disciplinary Guidelines



- Sanctions for non-compliant behavior
- Apply consistently and across levels
- Set levels of severity but also allow for flexibility
- OIG guidance on disciplinary procedures:
 - Set forth expectations
 - Identify what constitutes non-compliant behavior
 - Set forth possible disciplinary actions
 - More significant sanctions for intentional or reckless behavior

Response to Detected Behavior



- Correct problems
- Repayment of overpayments
- Other government disclosures (if necessary)
- Corrective Action Plan
- Monitoring
- Document Actions to Show Responsiveness

Your Compliance Plan



Your Compliance Plan



- Compliance is a process
 - Continually review
 - Is plan being followed?
 - Updates necessary?
 - Are staff and leadership aware of plan?
 - Assess for effectiveness
 - Set goals and benchmarks
 - Assess for new risks
 - Commit adequate resources



Your Compliance Plan



- Having an ineffective or outdated plan may be worse than not having a plan at all!



Recent DOJ and OIG Guidance



- Increased focus on if a program is effective, not what it looks like
- With new guidance, providers can expect that investigators will ask how programs' effectiveness was measured

Recent DOJ and OIG Guidance



- DOJ FAQ – questions covering 11 categories:
 - Analysis and Remediation of Underlying Misconduct;
 - Senior and Middle Management;
 - Autonomy and Resources;
 - Policies and Procedures;
 - Risk Assessment;
 - Training and Communications;
 - Confidential Reporting and Investigation;
 - Incentives and Disciplinary Measures;
 - Continuous Improvement, Periodic Testing and Review;
 - Third-Party Management; and
 - Mergers and Acquisitions.

Recent DOJ and OIG Guidance



■ OIG Resource Guide

- Reinforces that compliance is not one-size-fits-all
- Suggestions on methods by which effectiveness can be measured
- Continued focus and reinforcement of the seven elements:
 - Standards, Policies, and Procedures
 - Compliance Program Administration
 - Screening and Evaluation of Employees, Physicians, Vendors and other Agents
 - Communication, Education, and Training on Compliance Issues
 - Monitoring, Auditing, and Internal Reporting Systems
 - Discipline for Non-Compliance
 - Investigations and Remedial Measures

Encouraging Buy-In



- Explain to staff the benefits of effective compliance...
 - Increased efficiency
 - Maximized revenue
 - Happier patients

- And the consequences of non-compliance...
 - Employment sanctions
 - Fines and repayments
 - Prison!



Encouraging Buy-In



- Set “tone at the top”
- Transparency
- Resources

Additional Compliance Resources



- **OIG Compliance Resources**
 - <https://oig.hhs.gov/compliance/>
 - Work Plans, Advisory Opinions, Fraud Alerts, Settlements
- **State Attorney General actions**
- **Medicaid Fraud Unit actions**
- **Compliance organizations**
- **Internet – beware**
 - May be outdated
 - May not be from a qualified source

Additional Holland & Hart Resources



- *Healthcare Update and Health Law Blog*
 - Under “Publications” at www.hollandhart.com.
 - www.hhhealthlawblog.com
 - E-mail me at ksmcintosh@hollandhart.com

Additional Holland & Hart Resources



- Past webinars covering compliance topics and available through the *Health Law Blog*:
 - Stark
 - Anti-Kickback Statute
 - Civil Monetary Penalties laws
 - Physician Contracts
 - HIPAA
 - EMTALA
 - Antitrust

Questions?



Kelly S. McIntosh
Holland & Hart LLP
5441 Kietzke Lane, Second Floor
Reno, Nevada 89511
(775) 327-3004
ksmcintosh@hollandhart.com