

Third-Party Vendor Compliance Programs: The Value, the Need, the Risk

HCCA Compliance Institute
Session 602

Tuesday, April 19, 2016
1:00-2:00 PM



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Presentation Objectives

- Explore the **added value** and **business advantage** for healthcare entities in partnering with third-party vendors that have established a **robust** and **proactive compliance program**
- Assess **opportunities** and **inherent risks** associated with third-party vendors conducting proactive compliance/risk assessments of themselves and their clients
- Learn where third-party vendors as **business associates** may trigger **contractual and regulatory reporting obligations** for their clients



Outsourcing

- Outsourcing of services to third-party vendors is commonplace in today's healthcare marketplace
- Outsourced service lines may include:
 - Registration/Admission
 - Billing & Coding
 - Collections
 - IT/IS support
 - Medical Transcription
 - Analytics and Reporting
 - Professional Services; and
 - **Compliance**
- For purposes of this presentation, outsourced service vendor is broadly defined to include all entities that have entered into a contractual relationship with a healthcare entity to provide business functions or activities



Outsourcing – The Advantages



- Cost
- Expertise
- Flexibility
- Economies of scale
- Standardization
- Industry best practices



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Compliance = Competitive Advantage

- *Hypothesis* – Partnering with a third-party vendor that has a proactive and responsive compliance program can:
 - Add business value
 - Mitigate risk
 - Allow for standardization of policies and processes across multiple sites
 - Create investor/stakeholder confidence
 - Ensure heightened awareness of dynamic regulatory environment
 - Support collaboration and partnership in addressing compliance issues
 - Build management commitment to raising potential compliance concerns
 - Help the sales pitch for prospective clients and downstream entities



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Sample Mission Statement / Vendor Compliance Program

Foster an organizational culture that values, supports, and sets clear expectations for legal and ethical conduct through:

- **Proactive education and training** which promotes and informs compliance with applicable laws, regulations & guidelines
- Transparent and easy-to-understand **policies and procedures**
- Open and honest **communications and reporting** of concerns
- Routine **risk assessments** and standardized findings reports
- **Partnership and coordination** focused on legal, regulatory and financial risk mitigation, remediation and cost avoidance
- **Excellent "customer" service** and support - Always



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Outsourcing – The Risks

- Poorly defined scope and requirements
- Company's lack of oversight and control of vendor
- Vendor's lack of understanding of business entity's culture
- Vendor's lack of knowledge of legal and regulatory requirements



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Outsourcing – The Risks

An outsourced vendor's failures may result in operational, reputational and legal consequences to the client company



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And yet . . .

Consider value-add and business advantage of partnering with third-party vendors that have established a robust and proactive compliance program



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And keep in mind . . .

The additional guidance from, and general expectations of, HHS/OIG with respect to third-party vendors' development and maintenance of a compliance program.



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Third-Party Vendor Compliance Programs

- Since 1998, the OIG has had an "expectation" that third party medical billing companies (vendors) have a compliance program. "Publication of the OIG Compliance Program Guidance for Third-Party Medical Billing Companies." 63 Fed. Reg. 70138 (Dec. 18, 1998).
- More recently, the OIG has impressed upon Board members of health care entities the need to identify and assess risk to the organization, whether those risks are identified by internal or external sources. "Practical Guidance for Health Care Governing Boards on Compliance Oversight" (2015).



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Third-Party Vendor Compliance Programs

- CIAs entered into by the OIG typically define “Covered Persons” to include contractors, subcontractors and agents that perform Covered Functions.
- Reasonable to conclude that there is value in healthcare entities partnering with third-party vendors that have established robust and proactive compliance programs, including the ability to:
 - Provide written attestations of regulatory-related policies and procedures
 - Demonstrate security, privacy safeguards in handling PHI/confidential data
 - Ensure education and training in pertinent and high-risk areas of service lines



Balance Opportunities and Risks

Assess opportunities and inherent risks associated with third-party vendors conducting proactive compliance/risk assessments of themselves and their clients



Assessing Risk – Proactive and Reactive

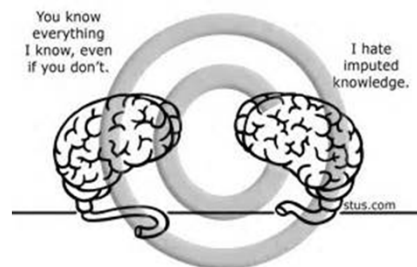
- *Hypothesis* – With expertise, efficiencies and commitment to ensuring compliance comes the obligation to assess and mitigate risk on a routine and as-needed basis.
- *Practical Considerations*
 - Assessing bandwidth of compliance staff, structure/scope of department
 - Partnering with Internal Audit, Legal, Risk Management
 - Ensuring leadership/management support
 - Evaluating contractual obligations
 - Determining responsibility to fix issue, address concern
 - Stratifying risk
 - Opening “cans of worms” has its pros and cons...



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Consider . . .

When does a third-party vendor trigger contractual and reporting obligations for its clients?



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Scope of Compliance Program?

- An outsourced service vendor's compliance program should be risk-focused and provide oversight and controls commensurate with the level of risk presented by the outsourcing arrangements in which the service vendor is engaged.
 - Coding & billing
 - EHR
 - Physician contracting
 - FMV
 - Commercial reasonableness



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How to Evaluate the Effectiveness of a Vendor's Compliance Program?

- Due diligence (business background, reputation and strategy)
- Performance measures
- Interviews with key stakeholders
- Operations and internal controls
 - training & education
 - privacy & security infrastructure
 - data management and controls
 - business resumption & contingency planning
 - systems development & maintenance
 - service support
 - workforce controls & background checks



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Don't Forget about Screening

- If a healthcare provider contracts with a third-party vendor that engages excluded personnel, the healthcare provider may be liable for CMPs (and be subject to exclusion)
- Know your vendors: "regularly" check (obligate vendor to check) excluded party data bases (OIG's LEIE; OFAC's SDN, GSA's SAM; state databases?)



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Contract Provisions and Considerations

- The terms of outsourced vendor service agreements should be defined in written contracts.
- Elements of outsource contracts and service agreements may include:
 - Outsourced services;
 - Term and timeframes;
 - Compliance with applicable laws, regulations, and regulatory guidance representations;
 - Training obligations of vendor employees;
 - The (in)ability to subcontract services and limitations (e.g., offshore);



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Contract Provisions and Considerations

- Insurance coverage requirements;
- Cost and compensation;
- Audit rights of company;
- Establishment and monitoring of performance standards
- Confidentiality and security of information;
- Indemnification and limits of liability.



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Vendors as Business Associates

Requirement

- Written arrangement with third party who accesses PHI in course of providing items or services

Audit Activities

- Does Covered Entity have HITECH-compliant BAAs with all of its applicable vendors? Standard Form? Signed?
- When and how often do they backup (your) data? Where is it stored? Offshore?
- Is there physical and/or logical separation of (your) data?
- Has vendor completed the required risk assessment?



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Vendors as Business Associates

Audit Activities

- Do they have a current HIPAA (health information privacy & security) Compliance Program in place?
- How often is their staff trained & informed about your company's HIPAA policies and programs?

(Non)negotiable provisions

- Insurance & Indemnification?
- Audit/monitoring?
- Breach notification (and mitigation)?
- Encryption?
- Offshore storage/access?



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So What's the Downside?

- Imputed knowledge?
- 60-Day Report & Return Rule
- Assessing responsibility
- Addressing liability

Upside
Downside



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Takeaways

- Healthcare entities should carefully evaluate a prospective third-party vendor's compliance program to determine commitment, capability, and cooperation
- OIG guidance and regulatory requirements direct the need for a third-party vendor to build, maintain, and evolve its compliance program
- In a competitive business environment with myriad outsourcing options, third-party vendors with active and proactive compliance programs yield positives and upside
- Proactive assessments create inherent risks, but healthcare entities and third-party vendors alike cannot turn away from addressing legal and regulatory issues
- Contracts help form the construct for partnership and commitment to a compliant culture and business operations; law and regulations rule the day



Questions

