

Data Driven
Compliance Risk Assessment

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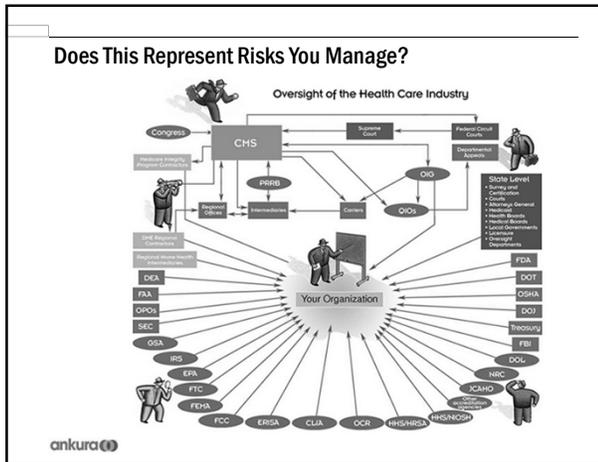
Why Risk Assessment?

Assure that you are appropriately using/ assigning compliance program resources

Assure that you are focused on and addressing the right risk areas

Help your leadership team define/ understand the strategy for your compliance program





What Risks Does Your Program Manage?

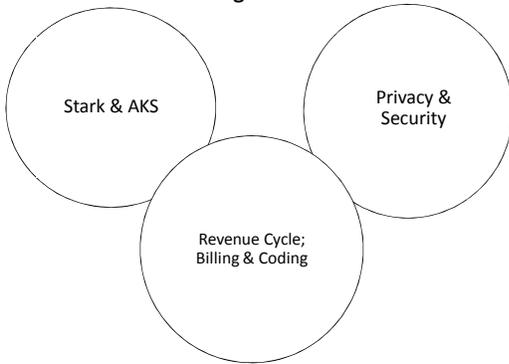
What would your leadership team say?

What are the characteristics of risks they want you to help them avoid?

Do you really have compliance program resources to manage every conceivable regulatory requirement?



What Risks Do You Manage?



Why Risk Assessment?

“(c) In implementing [a compliance program], the organization shall periodically assess the risk of criminal conduct and shall take appropriate steps to design, implement, or modify each [compliance program element] to reduce the risk of criminal conduct identified through this process.”

USSG §8B2.1.(c)



Why Risk Assessment?

“ . . . the OIG strongly encourages [providers] to identify and focus their compliance efforts on those areas of potential concern or risk that are most relevant to their individual organizations.”

OIG Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4858, 4859 (January 31, 2005)



Why Risk Assessment? New CIA Requirements

“Within 120 days after the Effective Date, [Organization] shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with the submission of claims for items and services furnished to Medicare and Medicaid program beneficiaries. The risk assessment and internal review process shall include:

- (1) a process for identifying and prioritizing potential risks;
- (2) developing an assessment plan to evaluate and respond to potential risks, including internal auditing and monitoring of the potential risk areas;
- (3) developing action plans to remediate potential risks; and
- (4) tracking results to assess the effectiveness of the risk assessment and internal review process, including any remediation efforts that [Organization] pursues.”

New risk assessment requirement from recent (2016) corporate integrity agreement.



How Does Compliance Risk Assessment Fit In?

	ERM	Internal Audit	Compliance
Objective & Focus	Strategic Risks	Financial Statement Integrity & Internal Controls	Compliance with Legal, Regulatory & Policy Requirements
Typical Owner	Chief Risk Officer/Chief Financial Officer	Chief Audit Executive	Chief Compliance Officer



Typical Risk Assessment Process

- Identification of compliance risks
- Evaluation of identified risks
 - Risk Impact: (Financial, Reputational, Legal)
 - Vulnerability: (Likelihood, Detectability)
- Prioritization of risks
- Plan/develop mitigation strategies
- Re-evaluate: Do it again!



Typical Risk Assessment Process

- Identification of compliance risks
 - OIG Workplan
 - Recent Settlements
 - Organization's Recent Experience
 - Interviews/Surveys of Leadership
 - Other



Risk Assessment Scoring Matrix					
Event	Impact to the Organization	Event	Vulnerability	Controls	
1	High or no reputational risk. Little or no financial or reputational impact (including legal fees/costs).	Little or no financial or reputational impact (including legal fees/costs).	Low risk, historical industry experience shows some regulatory compliance, but not fully automated processes. Some regulatory compliance - less likely to fail.	Process are built to be detected. Process to be directly experienced. Automated safeguards for identifying vulnerabilities.	Internal and external controls proven to be highly effective in mitigating all risk.
2	High reputational risk. Possible and significant patient, physician, consultant, talent.	Low to medium financial or reputational impact.	High risk, historical industry experience shows some regulatory compliance, but not fully automated processes. Some regulatory compliance - less likely to fail.	High risk that failure will not be detected. Limited safeguards in place to identify failure prior to occurrence. Partially automated process with moderate management oversight.	Actively audited and/or tested. Performance metrics are established, routinely reviewed and show little variation. Control plans and procedures exist. Employee training and competency established. Team prepared to manage the risk. Appropriately based on organizational risk management plans.
3	Moderate reputational risk. Possible and significant patient, physician, partner and/or consultant talent.	Low to medium financial or reputational impact.	Moderate risk of occurrence within next 12 months.	Moderate risk that failure will not be detected. Limited safeguards in place to identify failure prior to occurrence. Partially automated process with limited management oversight.	Periodically audited and/or tested. Corrective action plans developed and tested for effectiveness. Limited performance metrics established.
4	Significant negative patient coverage, significant patient, physician and/or consultant talent.	Low to medium financial or reputational impact.	Significant risk, likelihood of occurrence within next 12 months.	Highly difficult to detect prior to failure. Limited safeguards in place to identify failure. Manual process. Partially automated process, periodic management oversight.	Management Review and approval required. Process not audited or tested or infrequently audited or tested. Limited policy or procedure guidance.
5	Critical and/or severe negative patient coverage, significant patient, physician and/or consultant talent.	Critical condition and/or decision. High, immediate or near-term financial or reputational impact. High risk of occurrence. High risk of occurrence.	High risk of occurrence. Likely to occur in next 12 months. High risk of occurrence. High risk of occurrence. High risk of occurrence. High risk of occurrence.	Extremely hard to detect prior to failure. Highly automated with little or no human intervention, oversight or approval. No built-in safeguards, controls, or other mechanisms to identify anomalies prior to submission/completion.	No formal controls in place.

Culture & Conduct Risk

“Conduct Risk” is an amalgamation of

- **Organizational Culture**
(“tone at the top,” “mood in the middle” and “buzz at the bottom)
- **Conflicts of Interest**
(created by business models and strategies)
- **“People Risk”**
(created by behavioral incentives or disincentives, including compensation and disciplinary practices)

- **Periodic culture surveys may be the best way to measure**



Culture & Conduct Risk

- **Organizational Culture**
 - Are control functions valued?
 - Are policy & control breaches tolerated?
 - Are organization’s compliance processes proactively identifying risk and non-compliance events?
 - Are immediate managers effective role models of firm culture?
 - Are sub-cultures that do not conform to the desired culture identified and addressed?
- **Conflicts of Interest**
- **“People Risk”**
(created by behavioral incentives or disincentives, including compensation and disciplinary practices)



Culture & Conduct Risk

- **Conflicts of Interest**
 - Systematically identifying & inventorying conflicts
 - Resolving or reporting (where necessary) conflicts
 - Periodically testing conflicts management systems
- **“People Risk”**
 - Training
 - How people are compensated
 - Consistent discipline