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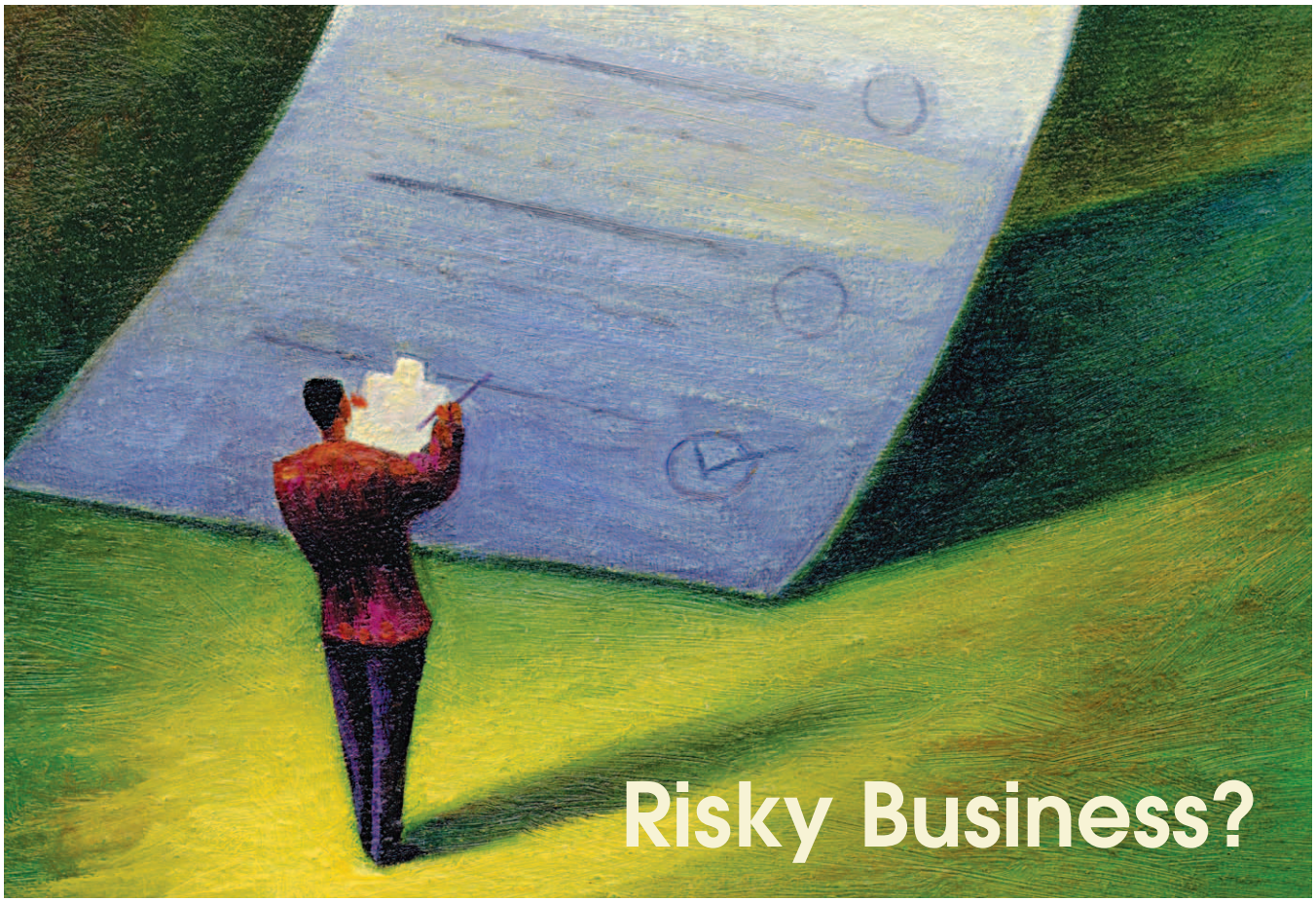

Risky Business?

Assessing Risks with A Risk Assessment Checklist

On February 14, 2012, the 2011 Health Care Fraud and Abuse Control Program (HCFAC) Report was released, touting a 4.1 billion dollar recovery in 2011, the largest recovery since the 1997 inception of HCFAC.[1] The government has proven a strong return on investment (ROI) with HCFAC producing a $5.1 to $1 ROI since 1997 and a $7.2 to $1 ROI for the years 2009 to 2011.[2] Generally, these recoveries were focused on: average wholesale price, other price-related allegations, alleged off-label marketing (both pharmaceutical and device), alleged violations of laws against self-referrals, alleged kickbacks, and other provider-related investigations and enforcement.[3] The HCFAC Report indicated that approximately $2.4 billion of the recovery resulted through civil health care fraud cases brought under the False Claims Act (FCA).

Under these aggressive, highly successful and ongoing enforcement efforts, pharmaceutical and device companies are often the target of multiple investigations and, in what seems to be an increasing trend, some companies are operating under multiple Corporate Integrity Agreements ("CIA"). Companies under CIAs, and those looking to avoid CIAs, must be ever vigilant in efforts to assess risk areas and adopt compliance program elements to address and mitigate those risk.

The following list is offered as a risk assessment checklist and does not purport to replace the need for a comprehensive internal and external independent assessment of an organization's compliance risk areas. Furthermore, each risk area provided requires additional review to identify sub-categories of risks relevant to each organization.

[1] http://www.hhs.gov/news/press/2012pres/02/20120214a.htmls

[2] The Department of Health and Human Services and The Department of Justice Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2011, p 8.

[3] Id, 20-22.

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RISK AREA CHART

AREAS OF RISK			
Anti-Kickback Statute/ False Claims Act Related:	Review Date	Findings	(1) Best Practice (2) Appropriate Controls (3) Action Plan Needed
1. Discounts and Rebates			
2. Grants/Charitable Contributions/ Third Party Meetings			
3. Health Care Professional (HCP) Agreements (Consulting, Advisory, Focus Groups, Research, Product Development (Royalties), Clinical Trials, Investigator Initiated Research, etc.) [Includes Fair Market Value Tools and Analysis]			
4. HCP Interactions – Business Courtesies, Educational Items, In-Services, Interactions with Medical Personnel			
5. Loaner Equipment			
6. Needs Assessment			
7. Prescriber Data			
8. Product Samples			
9. Product Support Services (Reimbursement)			
10. Scholarships and Educational Funds			
11. Sponsorships and Exhibits			
12. Support for Third-Party Educational or Professional Meetings (Cross-Reference Grants)			
13. Training and Education on Company Products (Speaker Programs)			
14. Unapproved Uses/Off-Label Promotion Controls			

RISK AREA CHART

AREAS OF RISK			
Foreign Corrupt Practices Act/Anti-Bribery Anti-Corruption:	Review Date	Findings	(1) Best Practice (2) Appropriate Controls (3) Action Plan Needed
1. FCPA/ABAC Compliance Program and Associated Policies and Procedures			
General Compliance (Policies/Procedures that Minimize Risks):	Review Date	Findings	(1) Best Practice (2) Appropriate Controls (3) Action Plan Needed
1. Adverse Event Reporting			
2. Annual Review of Compliance Program and Supporting Policies/Procedures			
3. Auditing and Monitoring			
4. Charitable Contributions Committee			
5. Chief Compliance Officer (Functions, Authority, Hierarchy, etc.)			
6. Compliance Committee			
7. Compliance Dashboards and Metrics			
8. Compliance Due Diligence, Acquisitions			
9. Compliance as Part of Employee Evaluations			
10. Conflict of Interest			
11. Corrective Action			
12. Disciplinary Action			
13. Ethics and Compliance Officer Reports to Board of Directors and Executive Session			

RISK AREA CHART

AREAS OF RISK			
General Compliance (Policies/Procedures that Minimize Risks):	Review Date	Findings	(1) Best Practice (2) Appropriate Controls (3) Action Plan Needed
14. Ethics and Compliance Website			
15. Exit Interviews			
16. Grants Committee			
17. Hotline			
18. Investigations			
19. Issue/Complaint/Resolution Process			
20. Management Accountability & Certifications			
21. Non-Retaliation/Non-Intimidation			
22. Patient Access Programs (Coupons, etc.)			
23. Reportable Events/Reports to Board			
24. Sales Representative Observations, Monitoring and Review			
25. Screening Requirements – Exclusion Lists: Office of Inspector General, General Services Administration; FDA Debarment, Office of Foreign Asset Control, Specialty Designated Nationals			
26. Social Media			

RISK AREA CHART

AREAS OF RISK			
General Compliance (Policies/Procedures that Minimize Risks):	Review Date	Findings	(1) Best Practice (2) Appropriate Controls (3) Action Plan Needed
27. Training and Education – Company Personnel and Board of Directors (Within 30 Days of Hire and Annually)			
28. Transparency Reporting – State and Federal Laws			
29. Vendor Compliance			
30. Vendor Credentialing Guidelines			
Privacy/Consumer Information:	Review Date	Findings	(1) Best Practice (2) Appropriate Controls (3) Action Plan Needed
1. Health Insurance Portability and Accountability Act (HIPAA)			
2. Health Information Technology for Economic and Clinical Health Act (HITECH)			
3. Interactions with Patients			
4. Sensitive Consumer Information and Applicable State Laws			
Reimbursement and Pricing:	Review Date	Findings	(1) Best Practice (2) Appropriate Controls (3) Action Plan Needed
1. Integrity of Data Used By State and Federal Governments to Establish Payment			
2. Interactions with Government Officials			

RISK AREA CHART

AR EAS OF RISK			
Reimbursement and Pricing:	Review Date	Findings	(1) Best Practice (2) Appropriate Controls (3) Action Plan Needed
3. Product Pricing and Discounts			
4. Reimbursement and Government Affairs			
5. Submission of Information to Compendia			
Unapproved Uses/Off-Label Marketing:	Review Date	Findings	(1) Best Practice (2) Appropriate Controls (3) Action Plan Needed
1. Product Related Functions			
2. Promotional Material Review			
3. Promotional Related Functions			
4. Publications			
5. Office of Medical Affairs, Database and Inquiry Tracking			
6. Sales and Marketing Compensation			
7. Training			

Sources:

1. AdvaMed Code of Ethics on Interactions with Health Care Professionals, Revised and Restated Code of Ethics, effective July 1, 2009.
2. Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and AstraZeneca Pharmaceuticals LP and AstraZeneca LP, Dated April 2010.
3. Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and DFine, Inc., Dated September 2011.
4. Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Merck & Co, Inc., Dated November 2011.
5. Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Novartis, Dated September 2010.
6. Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Novo Nordisk Inc., Dated May 2011.
7. Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Pfizer, Inc., Dated August 2009.
8. Deferred Prosecution Agreement between Smith and Nephew, Inc. and the United States Attorney's Office of New Jersey, Dated September 2007.
9. Deferred Prosecution Agreement between Zimmer, Inc. and the United States Attorney's Office of New Jersey, Dated September 2007.
10. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003).
11. PhRMA Code on Interactions with Healthcare Professionals, effective January 2009.

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