

Fundamentals of Health Care Compliance

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Compliance Programs

- Background
- Regulatory Standards
- Roles & Responsibilities
- Effective Compliance Oversight

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	Background
<p>Comprehensive Crime Control Act of 1984</p> <ul style="list-style-type: none"> • Created United States Sentencing Commission • Development of Organizational Sentencing Guidelines <ul style="list-style-type: none"> -Corporations -Partnerships -Labor unions -Pension funds -Trusts -Non-profit entities -Governmental units 	
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	Background
<ul style="list-style-type: none"> • Two Key Purposes “just punishment” & “deterrence” • Incentives offered for organizations to detect and prevent crime • Culpability score • Chapter 8 Part B – Remedying Harm from Criminal Conduct and Effective Compliance and Ethics Programs (Come back to this later) 	
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	Background
University of Pennsylvania	
<ul style="list-style-type: none"> • December 12, 1995 • \$30 million clinical practices settlement • Various claims and allegations under False Claims Act • Placed hospitals, physicians and other health care providers on notice • Followed by many other enforcement actions 	
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	Background
Fraud Statistics 10/1/86-9/31/08	
<ul style="list-style-type: none"> • DOJ/OIG Recoveries \$14.2 billion • Criminal Convictions 5300+ • 2007 Convictions 560 • \$6.00 in recoveries for every dollar spent! 	
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	Background
HIPAA – Health Insurance Portability and Accountability Act	
<ul style="list-style-type: none">• PL 104-191, effective August 21, 1996• Improve health insurance coverage and portability• Reduce administrative costs• Privacy and security standards	
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	Background
<ul style="list-style-type: none">• Reduce fraud<ul style="list-style-type: none">– Appropriated \$548 M to FBI over 7 years– Each year thereafter \$114 M• Defines “Federal Health Care Offense”<ul style="list-style-type: none">– Expanded reach of federal enforcement activity to include fraud related to any “health care benefit program”, rather than simply federally funded	
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	Regulatory Standards
<p>Caremark Case Delaware Chancery Court case in which the court concluded that a director’s fiduciary obligation included:</p> <ol style="list-style-type: none"> (1) a good faith effort to assure that an adequate compliance program exists; and (2) that information regarding the organization’s compliance with laws be brought to the board’s attention in a regular and timely manner. <p><u>In re: Caremark International Inc. Derivative Litigation.</u> 619 A2d 959 (Del. Ch. 1996)</p> <p>HCCA</p>	

	Regulatory Standards
<p>§8B2.1 Effective Compliance and Ethics Programs (attached)</p> <ul style="list-style-type: none"> • “To have an effective compliance and ethics program,... an organization shall – <ul style="list-style-type: none"> – Exercise due diligence to prevent and detect criminal conduct; and – Otherwise promote an organizational culture that encourages ethical conduct and a commitment to compliance with the law.” – “7 Elements” <p>HCCA</p>	

	Regulatory Standards
<p>1. Establish Standards</p> <ul style="list-style-type: none"> • Code of Conduct • Conflict of Interest policy • Structural (program operation) policies and procedures • Substantive (high risk areas) policies and procedures <p>HCCA</p>	

	Regulatory Standards
<p>2. High Level Oversight</p> <ul style="list-style-type: none"> • Board must be knowledgeable about content & operation and exercise reasonable oversight of implementation and effectiveness of compliance program • Responsibility for <u>program</u> assigned to a specific high individual (emphasis added) • Person(s) involved in day-to-day operation shall be given adequate resources, appropriate authority and direct access to board or board committee. <p>HCCA</p>	

	Regulatory Standards
<p>3. Screening</p> <p>“Reasonable efforts not to include within the substantial authority personnel ... any individual whom the organization knew or should have known ...has engaged in illegal activities or <u>other conduct inconsistent with an effective compliance and ethics program.</u>” (emphasis added)</p> <p>HCCA</p>	

	Regulatory Standards
<p>4. Training & Education</p> <ul style="list-style-type: none"> • “To communicate in a practical manner its compliance standards and procedures” • “... conducting effective training ... appropriate to such individuals respective roles and responsibilities” <p>“Individuals” means board, management, employees and, as appropriate, agents”</p> <p>HCCA</p>	

	Regulatory Standards
<p>5. Monitoring, Auditing & Reporting</p> <ul style="list-style-type: none"> • Monitoring and auditing to detect criminal conduct • Evaluate the effectiveness of the compliance & ethics program • Maintain a system for reporting potential violations without fear of retaliation and that allows for anonymous reporting <p>HCCA</p>	

	Regulatory Standards
<p>6. Aligned Incentives</p> <p>“The organization's compliance and ethics program shall be promoted and enforced consistently throughout the organization through</p> <ul style="list-style-type: none"> (A) appropriate incentives to perform in accordance with the compliance and ethics program; and (B) appropriate disciplinary measures for engaging in . . . and for failing to take reasonable steps to prevent or detect criminal conduct” <p>HCCA</p>	

	Regulatory Standards
<p>7. Respond appropriately</p> <ul style="list-style-type: none"> • Prompt remediation (including repayment of overpayments) 42 U.S.C. 1320a - 7(b)(A) 3 • Process or procedure changes • Education or re-education <p>HCCA</p>	

	Roles & Responsibilities
<p><u>The Challenge</u></p> <ul style="list-style-type: none"> • People don't view themselves as unethical • Boards & Management don't know what they need to do • Incentives are skewed <p>HCCA</p>	

	Roles & Responsibilities
<p>Ethics</p> <ul style="list-style-type: none"> • Perception: • Reality: <ul style="list-style-type: none"> – Cheating <ul style="list-style-type: none"> • high school • college • MBA – Resumes – Workplace 	
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	Roles & Responsibility
<p><u>Role of the Board</u></p> <ul style="list-style-type: none"> • Define scope of the program • Align incentives • Approve key policies and procedures • Require periodic, substantive reporting by management • Ask questions! ! ! <p>Tip: Add compliance expertise to board or appropriate committee.</p>	
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	Roles & Responsibility
	<p data-bbox="414 331 828 373"><u>Role of Management</u></p> <ul data-bbox="414 409 1144 672" style="list-style-type: none"> <li data-bbox="414 409 1079 451">• Actively promote/support program <li data-bbox="414 472 1096 514">• Ensure implementation of program <li data-bbox="414 546 1144 588">• Create culture that permits questions <li data-bbox="414 619 1031 661">• Hold subordinates accountable <p data-bbox="414 693 1193 871">Tip: It's management's job to implement the program and ensure compliance. The role of the compliance officer is to ensure management has the tools & resources.</p> <p data-bbox="337 913 414 945">HCCA</p>

	Roles & Responsibility
	<p data-bbox="414 1213 966 1255"><u>Role of Compliance Officer</u></p> <ul data-bbox="414 1291 1185 1680" style="list-style-type: none"> <li data-bbox="414 1291 1153 1438">• Design (and redesign) program with input from management (operations), employees, peers and experts <li data-bbox="414 1449 1071 1585">• Develop policies and procedures <ul data-bbox="462 1491 1006 1585" style="list-style-type: none"> <li data-bbox="462 1491 868 1533">– Structural → OSGs <li data-bbox="462 1543 1006 1585">– Substantive → high risk areas <li data-bbox="414 1585 1185 1680">• Develop/acquire educational programs applicable to targeted job functions <p data-bbox="337 1785 414 1816">HCCA</p>

	Roles & Responsibility
<p data-bbox="414 346 1104 388"><u>Role of Compliance Officer (Cont.)</u></p> <ul data-bbox="422 430 1112 703" style="list-style-type: none"> •Simplify complex, clarify ambiguous •Respond to environmental changes •Monitor and report on execution •Have the difficult conversations <p data-bbox="337 913 414 945">HCCA</p>	

	Roles & Responsibility
<p data-bbox="414 1218 787 1260"><u>Role of Employees</u></p> <ul data-bbox="414 1270 1169 1701" style="list-style-type: none"> • Participate in program – complete education, follow P & Ps • Seek advice when there are questions • Bring issues of non-compliance to attention of appropriate people <ul data-bbox="454 1522 690 1596" style="list-style-type: none"> – Internal – Anonymous • Cooperate in investigating/fixing identified problems <p data-bbox="337 1785 414 1816">HCCA</p>	

	Roles & Responsibility
	<p><u>Keep the Program Simple</u></p> <ul style="list-style-type: none">• Tackle highest risks first• Give management/employees clear direction<ul style="list-style-type: none">– Ambiguity paralyzes– Specificity enables accountability• Work within limits of organization's resources <p>HCCA</p>

	Effective Board Oversight
	<p><u>Align Incentives</u></p> <ul style="list-style-type: none">• Incentive compensation• Transparency• Performance evaluation• Recognition• Keeping promises <p>HCCA</p>

	Effective Board Oversight
<p><u>Properly Positioned Compliance Officer</u></p> <ul style="list-style-type: none"> •Reports to board (committee) and/or CEO •Regular executive sessions •Reasonable severance package •Minimize conflicting responsibilities •Educated compliance officer <p>HCCA</p>	

	Effective Board Oversight
<p><u>Specific, Measurable Objectives</u></p> <ul style="list-style-type: none"> ▪ <u>Structural (program operation)</u> <ul style="list-style-type: none"> — P & Ps - orientation to program and P&Ps; development or review of P&Ps, adherence to P&Ps — High Level Oversight – Board Oversight, Sr. Mgmt participation in meetings, audit exit conferences, compliance meetings, compliance officer member of Sr. Management, etc — Education - completion of compliance and ethics education, completion of job specific education programs, ethics scenario discussions in staff meetings, etc — Screening – background checks, exclusion checks <p>HCCA</p>	

	Effective Board Oversight
	<p><u>Specific, Measurable Objectives</u></p> <p>▪<u>Structural (program operation) (cont.)</u></p> <ul style="list-style-type: none"> — Investigation/Reporting - documentation of employee complaints and hotline calls, prompt investigation and response to complaints/hotline calls — Monitoring/Auditing - completion of audit/monitoring activities, scores on audits (accuracy of process), completion of reports, tracking & submission of data, etc — Remediation – correction of identified mistakes (refunds, data/reporting errors, etc), completion of corrective action plans (training, P&P development/modification, implementation of new/different control processes, etc) <p>HCCA</p>

	Effective Board Oversight
	<p>•Risk Assessment Process</p> <ul style="list-style-type: none"> –How are risks identified (new laws/ rules, settlements, case law, management questionnaires/ interviews, audit findings, etc.) –How are risks rated/evaluated <p>HCCA</p>

	Effective Board Oversight
	<ul style="list-style-type: none"> ▪ Substantive <ul style="list-style-type: none"> ➤ General <p>Tax, FLSA, Environmental, Antitrust, etc.</p> ➤ Healthcare Specific <p>anti-kickback, Stark, false claim, (including documentation, medical necessity, coding & billing, quality of care standards), licensure & certification, HIPAA, tax-exemption (charity care, billing & collection, intermediate sanctions, lobbying and political activity, loss of bond tax-exemption)</p> <p>Tip: Develop a compliance scorecard for key business unit executives that addresses structural components and key substantive risks. These objectives must be specific, objectively measurable and will be most effective if it has a material impact on the performance evaluation and/or incentive compensation process. See attached example.</p> <p>HCCA</p>

	Effective Board Oversight
	<p style="text-align: center;">Management & Board Reporting – Written Reports</p> <ul style="list-style-type: none"> • <u>Written Reports</u> – purpose is to inform, report and educate <ul style="list-style-type: none"> ➤ Issues ➤ Investigations (internal & external) ➤ Annual work plan progress ➤ Key metrics ➤ Recent developments <p>HCCA</p>

	Effective Board Oversight
<p style="text-align: center;">Management & Board Reporting – Oral Reports</p> <ul style="list-style-type: none"> • <u>Oral Reports</u> <ul style="list-style-type: none"> ➤ Highlight <ul style="list-style-type: none"> – new investigations/issues – new reports/tools – Key messages ➤ Respond to management/board questions ➤ Ask management/board if they have questions <p>HCCA</p>	

	Effective Board Oversight
<p style="text-align: center;">Management & Board Reporting – Minutes</p> <ul style="list-style-type: none"> ➤ Purpose: To reflect topics, deliberations and actions in meeting and demonstrate that participants are effectively fulfilling their role ➤ Outline <ul style="list-style-type: none"> – General topic area – Issues – Questions/deliberations – Action <p>See <u>Corporate Minute-Taking: A General Counsel's Guide</u> by Michael Peregrine & Russ Hayman http://www.mwe.com/info/pubs/HLN Analysis0106.pdf</p> <p>HCCA</p>	

Q& A

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