


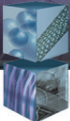
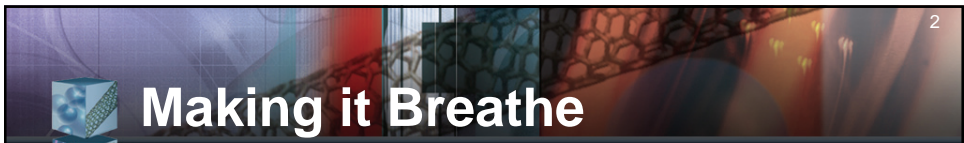
DGC NYC Incorporated 2008 Medicaid Drug Rebate Program March 11 – 12, 2008

Implementation of an Effective
Compliance Program
Robert E. Slavkin
Foley & Lardner LLP





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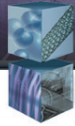
Making it Breathe

- How do you create a program that integrates into your daily operations?
- How do you breathe life into it?



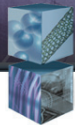
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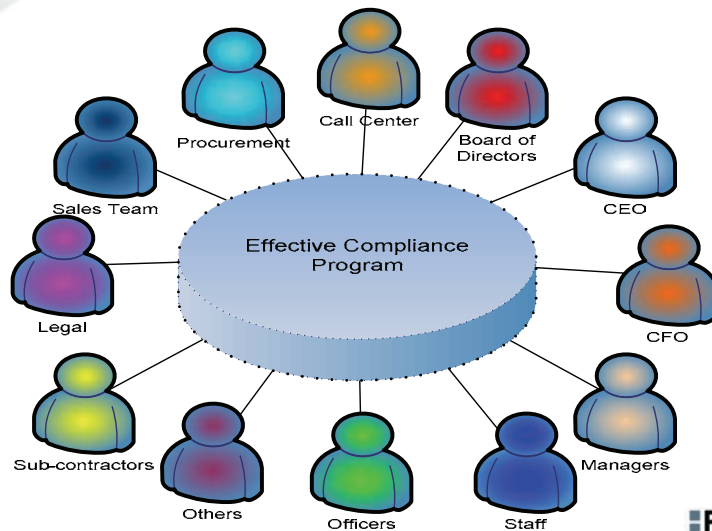


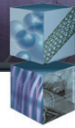
Making it Breathe

- How do you get buy-in?
- The \$64,000 question
- Step One: A Strong Compliance Program



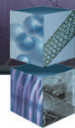
Buy-in from EVERYONE





Who's In Charge Here?

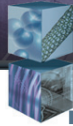
- The Compliance Officer
- The Compliance Committee
 - They report to: The CEO and Board of Directors
 - The Job: responsible for developing, operating, and monitoring the Fraud and Abuse program



Who's In Charge Here? (continued)

- Compliance Officer and Compliance Committee must be in-house
 - this function may not be subcontracted

Seven Essential Elements of a Compliance Plan ⁷



- Standards and Procedures
- Oversight
- Education and Training
- Monitoring and Auditing
- Reporting
- Enforcement, Discipline and Incentives
- Response and Prevention



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Financial Support ⁸




- Development/Start-up
- Educational Materials
- Staffing
- Ongoing Operations



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Fraud, Waste and Abuse Program a Part of a Compliance Plan Should include:

- Written policies and procedures and standards of conduct :
- Goal:
 - Demonstrate the organization’s commitment to comply with all applicable Federal and State standards

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Written Policies and Procedures

Written policies and procedures should include, but not be limited to:

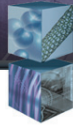
- Code of Conduct
 - commitment to comply with
 - Statutory;
 - Regulatory;
 - Program requirements;

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Written Policies and Procedures

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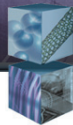
- Policies and procedures:
 - To respond to potential violations of Federal and State laws and regulations
 - To identify overpayments at any level within the network and the repayment to CMS where appropriate
 - To coordinate and cooperate with MEDICs, CMS and law enforcement; and
 - To review exclusion lists for the sponsor's employees and contractors.

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Questions:

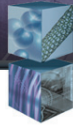
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- What are responsibilities for compliance policies and procedures at contracted entities?
- What issues do entities face in meeting these responsibilities?
- What are some effective methods that entities should consider to ensure that appropriate p&p are in place downstream?

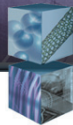
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Effective Training and Education

Effective *training and education* on fraud, waste and abuse that would address pertinent laws related to fraud and abuse (for example, anti-kickback provisions and False Claims Act provisions) and common fraudulent schemes or “vulnerabilities”.



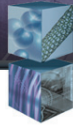
Effective Training and Education

Training and education programs should include:

- > A description of the compliance program;
- > Review of policies and procedures;
- > Overview of process for asking compliance questions;
- > Review of the disciplinary guidelines for non-compliant behavior;
- > Review of policies related to contracting with the government; and
- > Overview of plan’s monitoring and auditing workplan

Effective Training and Education

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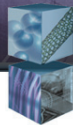
Specialized training also is required for employees on issues posing compliance risks based on their job functions (e.g. marketing, payment reconciliation, pharmacy claims submission, etc.)

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Questions:

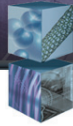
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- What are responsibilities for effective training at contracted entities?
- What issues do entities face in meeting these responsibilities?
- What are some methods for entities to consider to ensure effective downstream training?

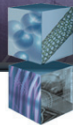
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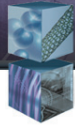
Effective Communication

- Procedures should be in place to protect the anonymity of complainants and protect whistleblowers from retaliation
- Concerns and risks should be reported via independent mechanisms, e.g., hotlines, suggestion boxes, employee exit interviews, emails or any other forum that promotes information exchange
- Effective communication can be enhanced by putting in place a complaint tracking system, with explicit process for handling beneficiary complaints
- Consider methods for ensuring effective communication at downstream contractors – what are some suggestions?



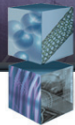
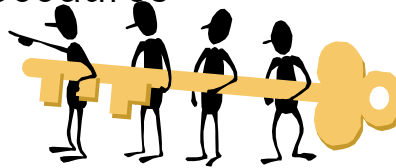
Enforcement of Standards

- Well-publicized disciplinary measures
 - What are examples?
- What are methods for publicizing standards at downstream contractors?
- Involvement of management
 - Plan
 - Downstream



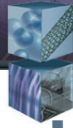
Monitoring and Auditing

- Program Effectiveness
- Internal “Audits”
- Compliance “Reviews”
- Outline Audit Procedures
- Staff Training



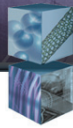
Monitoring and Auditing

- Monitoring activities refer to reviews that are repeated regularly during the normal course of operations
- An audit refers to a more formal review of compliance with a particular set of internal or external standards
- Sponsors should develop a monitoring and auditing work plan that addresses risks associated with the MA and Part D benefits



Monitoring and Auditing

- Suggestions and resources for internal audit work plans:
 - Review of potential high risk areas (e.g., enrollment, denials, marketing)
 - Unannounced internal audits or “spot checks”
 - CMS Call Letter
 - Audit Guides
 - CMS’s Parts C and D CAP Data
 - OIG Workplan
 - OIG advisory opinions

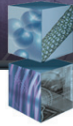


Monitoring and Auditing

- Review areas previously found non-compliant to determine if corrective actions have been performed, effective to address underlying problem.
- Consider use of objective, independent auditors
- Address potential risk areas for vendors, PBM, other downstream contractors
- Role of internal audit department

Prompt Responses to Detected Offenses

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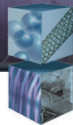
- Timely inquiries into reported misconduct
- Practical issues when misconduct alleged at downstream entity level
- Processes for establishing corrective action plans at downstream entity levels

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Fostering Everyday Practice

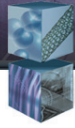
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- Questions to ask in creation of a plan:
 - What would be included in the training?
 - How would competency be documented?
 - How would competency be reviewed?
 - What updates?
 - What intervals?

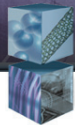
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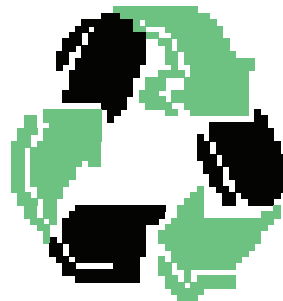


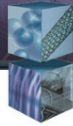
Fostering Everyday Practice

- Silent Shoppers;
- Call Monitoring;
- “Ride Along” training of sales force & follow up Quality/Customer Satisfaction surveys;
- If cross-selling other products, look at statistical data around how many cross-sold products, any patterns?
- Demographic profiles of sales accounts



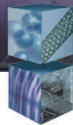
Continuous Improvement





Pursuing Internal Compliance

- Plan Marketing Dos and Don'ts
- Plans' Sales Force
- Practical Implementation of Marketing Activities
- Potential Compliance Issues
- Potential Compliance Strategies

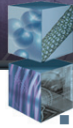


Plan Marketing Dos and Don'ts

- Plans May:
 - Use employees, subcontractors, independent contractors to market the Plan
 - Conduct outbound telephone marketing, in accordance with federal and state laws
 - Provide gifts of “nominal value” for event attendance, so long as the gift is not contingent on enrollment



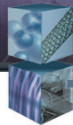
Plan Marketing Dos and Don'ts



- Plans May Not:
 - Engage in “cherry-picking”
 - Undertake door-to-door solicitation
 - Mislead beneficiaries or misrepresent the Plan
- Plans May Not Offer Inducements to Medicare Beneficiaries to Select The Plan
- Plans May Not Violate the Federal Anti-Kickback Statute or Similar Federal or State Laws




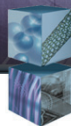
Plans' Sales Force



- Plans Must be Marketed by Licensed Insurance Salespersons if State Law Requires
- Determine activities regulated by the state
 - Determine licensure, other regulatory requirement
 - Monitor compliance!
 - For Example:
 - Florida licensure requirements:
 - Pre-licensing course completion
 - Pass a licensure exam
 - Submit application that Includes:
 - Applicant's full name, address, age, ss #
 - Proof of completion or about to complete prelicensing course
 - Information on whether the applicant has had an insurance sales license revoked
 - Whether the applicant is indebted under an agency contract
 - Proof applicant meets requirements for type of license sought
 - Additional information regarding experience, education, ability
 - Fingerprinting

Practical Implementation of Marketing Activities

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Web Site Guidelines

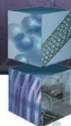
- Must have a dedicated Prescription Drug Benefit web site or page, including name of Part D plan
- Must have font size 12 coded into its site
- Part D Plan toll-free customer service number, TTY/TDD number, physical or Post Office Box address & hours of operation
- Description of services, benefits, applicable terms and conditions, premiums, cost sharing, conditions associated with receipt or use of benefits 60 day notice regarding formulary changes, pharmacy access information, out of network coverage, grievance, appeals & exceptions policies
- Links for Summary of Benefits, Enrollment Instructions & Forms, Evidence of Coverage & Privacy Notice

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Practical Implementation of Marketing Activities

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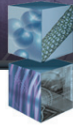


Evidence of Coverage Must Include

- Plan service area
- Annual deductible amount; initial coverage limit; cost sharing under initial coverage limit and the cost sharing between initial coverage limit and annual out of pocket threshold.
- Major exclusions and limitations, including UM, generic substitution and any other formulary restrictions; emergency and urgent care
- All monetary limits as well as restrictive policies that might impact access to drugs or services
- Quality assurance policies & procedures, including UM and DTM
- Part D Plans' contract is renewable annually so coverage beyond 1 year not guaranteed
- Define & explain formulary & how to obtain exceptions to formulary or tiered cost structures; EOBs for prescription drug benefits used
- Availability of limited income subsidies and rights of appeal

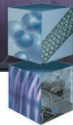
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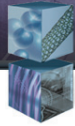
Potential Compliance Issues

- Matching Oral with Written Communications Regarding Plan Benefit Package,
 - Enrollment/disenrollment
 - Formulary coverage and cost-sharing obligations
 - Coverage determinations and appeals
- Work Force Education/Competency & Qualifications
- Brokerage Activities
- Call Center Environment
 - Training materials
 - TSF/ASA requirements
 - Performance standards
 - Documentation/risk management



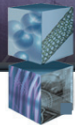
Potential Compliance Strategies

- Marketing Department Self-Monitoring
 - Develop and maintain policies and process for internal review of ALL activities and materials
 - Provides framework, structure for organizing marketing activities and meeting CMS' regulatory requirements and time frames
 - Assists in maintaining consistent messages in marketing materials
 - Enables monitoring of all activities (performed by Plan and by contractors)
 - Can prevent inadvertent violations
 - Train and test employees and contractors engaging in marketing activities
 - Many contractors unaware that Medicare marketing activities are so highly regulated, especially compared to commercial plans
 - Provides an opportunity for individuals to ask questions, get clarification
- Compliance Department Oversight and Auditing
 - Routine and unannounced monitoring of marketing materials, "secret shoppers"
 - Prevents/corrects inappropriate activities
 - Identifies areas where additional training is required



Pursuing External Compliance

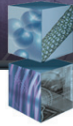
- Identifying the Players
 - Agents, brokers and other marketing contractors
 - Providers
- Understanding What Each Player May, May Not Do and Say
- Compliance Strategies to Prevent, Detect and Correct Issues



Agents, Brokers and Other Marketing Contractors

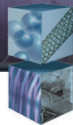
- Independent Agents and Brokers
 - Similar Issues and Employed Agents and Brokers
 - Significant Enforcement Scrutiny of these Entities
- Other Marketing Contractors
 - e.g. Telemarketers and Printing Companies
 - ◆ Strict oversight and training
- Both Outbound Marketing and Inbound Enrollment Calls
 - ◆ Routine Monitoring of Print Materials
 - ◆ HIPAA Issues

Compliance Strategies to Prevent, Detect, and Correct Issues



- Periodic Training and Testing of Contractors
- Practical Monitoring Tools
- Consider Including in Provider, Contractor Contracts Provision(s) Addressing Marketing Activities
 - Specifically, require compliance with the Guidelines
 - Require Plan oversight and/or approval of all marketing activities
 - Require Plan approval of all marketing materials prior to use

Potential Penalties For Non-Compliance

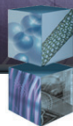


- CMS May Impose Sanctions on Plans That Violate the Applicable Regulations, Including Marketing Guidelines
 - Civil money penalties (“CMPs”) ranging from \$10,000 to \$100,000, depending on the violation
 - Suspension of enrollment
 - Suspension of payment
 - Suspension of marketing activities
 - Denial of contract renewal or contract termination
- Less Severe Sanctions Include “Cease and Desist” Letters and Warnings Against Similar Actions
- **BEWARE: States Like to Get Into the Act, too.**



Potential Penalties For Non-Compliance

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- Bases for Imposing Sanctions Include
 - “Failure to substantially carry out” the terms of the contract with CMS
 - Carrying out the contract “in a manner that is inconsistent with the effective and efficient implementation” of the MA or Part D program
 - CMS determines that the Plan Sponsor “no longer meets the requirements . . . for being a contracting organization”
- Marketing Violations Also Can Be Basis for Investigation by the Medicare Drug Integrity Contractors (MEDICs), United States Attorneys, State Insurance Departments, State Attorney Generals

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Other “Hot” Risk Areas

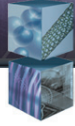
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- Denials
- Disenrollment
- Data Security
- Relationships with pharmaceutical manufacturers

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Robert E. Slavkin, Esq.
Foley & Lardner LLP
111 North Orange Avenue
Suite 1800
Orlando FL 32801
(407) 436-7656
RSlavkin@foley.com