Managed Care Organizations and Measuring Compliance Program Effectiveness:

Review the Tools Used by Hospitals, Health Plans and Providers to Measure Effectiveness and See How They Work

HCCA COMPLIANCE INSTITUTE

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Objectives

- ❑Introductions
- ❑Compliance Program "Effectiveness" – How to use the HCCA-OIG Program Effectiveness Resource Guide (2017)
- ❑Special Focus Areas
  - Lines of Communications – What makes a great Compliance Officer?
  - FDRs – How do you manage your vendors? How can hospitals and health plans collaborate?
  - Risk Assessment – How to get started and what tools do you use?
  - HIPAA – Are you ready if an investigation, audit or breach comes your way?
- ▪Top Takeaways
  - Prioritize your risks.
  - Trust but Verify!
  - Communication is the Key to Success and Effectiveness.

Positive Compliance Outcomes

Positive Compliance Outcomes

- Independent Consultant – Working with Managed Care Organizations, primarily Health Plans.
- Over 25 years of experience in Medicare, Medicaid, and Commercial Insurance Programs.
- Expertise in compliance program activities such as development and implementation of Compliance Programs, CPE Effectiveness audits, Operational areas efficiency reviews, SIU/FWA functions, and HIPAA Privacy and Security reviews.
- Prior position: Senior Vice President and Chief Compliance Officer at Affinity Health Plan in the Bronx, NY with responsibilities for Corporate Compliance, Internal Audit , Legal, and Federal and State Regulatory Affairs.

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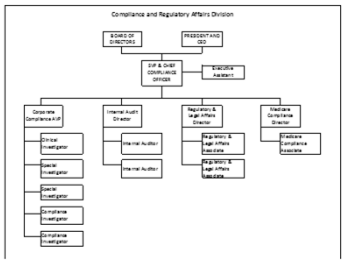
Health Plan Compliance *Organization*



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Key Compliance Relationships

- CCO had a direct reporting line to the CEO and the Board of Directors and was a member of the Executive Leadership Team.
- Participated in other Board Committees/Sub-Committees:
  - Audit Committee
  - Finance Committee
  - Quality Management Committee
  - Compliance Sub-Committee – Staffed the Committee.
- Lead the Internal Compliance Committee. Participated in sub-committees: FWA, Medicare Operations Workgroup, Vendor Management Oversight, Member Services
- Prominent internal compliance relationships: Finance, Information Management, Human Resources, Provider Relations, Network Management, Pharmacy, Claims, Member Services

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North Memorial Health Organization Structure and Compliance Resources

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North Memorial Health

- Located in Minneapolis/St. Paul, MN
- 2 Hospitals
  - North Memorial Health Hospital (Level 1 Adult trauma center)
  - Maple Grove Hospital (Community Hospital; busy L&D department)
- Over 25 primary care, urgent care and specialty care clinics
- Emergency Medical Services
  - Ground ambulance and air care
  - Serves MN and WI; Largest EMS provider in Minnesota
- Over 5,000 team members
- Over 400 employed providers (about 25% of total medical staff is employed)

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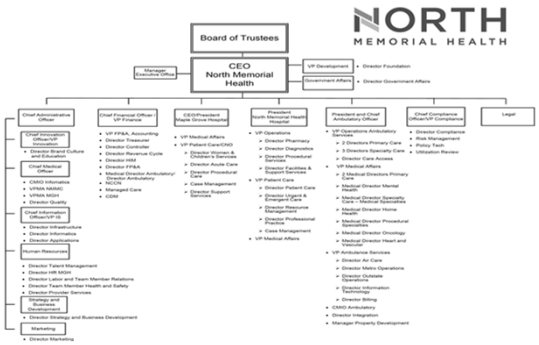

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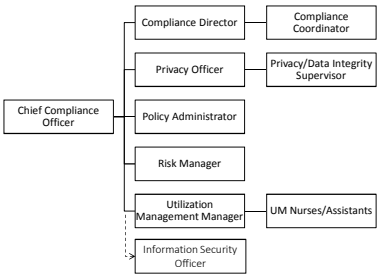
2018 Compliance Department Structure



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Key Compliance Relationships

- ❑CCO is a member of the Corporate System Leadership Team
- ❑Dotted line reporting to Chair of the Audit/Finance Committee of the Board of Trustees
- ❑Compliance Committee Structure:
  - Executive Compliance Committee
  - Revenue Cycle Compliance Committee
  - External Audit Response Team
  - Regulatory Review Group
  - Operational Department Committee (Ambulance, Pharmacy, Hospice, Lab)
- ❑Prominent internal compliance relationships: Revenue Cycle, Financial Controller, Information Technology, Human Resources, Health Information Management, Pharmacy, Medical Staff

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Measuring Compliance Program Effectiveness: A Resource Guide

HCCA-OIG MARCH 27, 2017

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Using the Resource Guide

The following slides are a summary of the guide that seeks to provide an overview of how to work with the guide in reviewing and developing how you measure the effectiveness of your compliance program.

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Standards, Policies and Procedures

Measuring the effectiveness of organizational standards:

- Access
- Accountability
- Review/Approval Process
- Quality
- Assessment

Resource guide pages 2-7.

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Code of Conduct

- ❑Does the code reflect current Mission, Vision, Value statements?
- ❑Was senior leadership involved in the creation and review of the Code of Conduct?
- ❑Does Human Resources actively use the Code of Conduct?
- ❑Is it used throughout the organization during training activities? Is it integrated into other organizational "customer service" tools?
- ❑How is it accessed?
  - Online?
  - Has marketing created a branded summary/version that can be displayed easily?
  - Do staff attest to reading and understanding it?
- ❑How often is it reviewed and updated? What is the process?

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Compliance Plan Documents

- ❑What is the intended purpose?
  - Audit/external stakeholders?
  - Internal stakeholder understanding of scope of compliance plan?
  - Tool for compliance staff?
- ❑What is the review/approval process? Are internal stakeholders involved?
- ❑Is it easily accessible to internal stakeholders/staff?
- ❑How does the CCO use the compliance plan during the year?

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Policies and Procedures

- ❑Content of policies
  - Consider developing a "policy on policies"
  - Grid defining policy, procedure, guidelines, attachment, protocol, etc.
  - Standard templates (outline format)
  - Development of a definition dictionary that applies to terms used in policies/procedures
- ❑Policy approval process
  - How are policies and/or procedures reviewed by all stakeholders impacted by the policy?
  - How is internal consistency among policies achieved during review process?
  - Defining "final" approval bodies
  - Are policy owners responsible for completing and implementation plan prior to policy approval?
  - How are new/reviewed policies communicated throughout the organization?
- ❑Policy maintenance
  - Do you have policy software? If not, what process exists to maintain version control?
  - Is there a dedicated resource for policy administration?
  - How are policy owners trained to use the policy system?

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Maintaining Compliance Department Policies

- ❑ Review process for Compliance Plan and Compliance P&Ps?
  - Process for "tracing" current policy/procedure content
  - Process for ensuring current regulatory citations in policies – which stakeholders are involved?
  - Use regulatory standards; if want a higher standard, use "best efforts language"
- ❑ Create an Annual Compliance Department Activity Tracker to assure you address all activities and commitments
- ❑ Maintenance/validation of Activity Tracker
  - Routine stakeholder communication regarding progress

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2018 Compliance P&P Activity Tracker

#	Policy Requirement	P&P Ref	Page #	Owner	Verification Method	Verified by	Start Date	Expected Completion Date	Actual Completion Date
1	Establish a Service Verification Policy and assure a quarterly verification that services were delivered to Members.	COM 10	6	J. Smith	Select 50 paid claims monthly. Contact member to validate services were delivered. Must make three attempts at different times of the day.	J. Doe	2/1/18	3/15/18	
2	Ensure that all employees are aware of the standards for business conduct and ethical behavior that is expected CPHL.	COM 2	10	J. Doe	Select 10 new employees within the last quarter and validate the Code of Conduct acknowledgement form is complete and on file.	M. Smith	4/15/18	4/30/18	
3	Ensure Conflict of interest Dislosure Forms have been completed for all Management staff and above.	COM 3	12	H. Brown	Randomly select five management staff and validate: 1. Validate COI training was completed with sign-in sheets, and 2. The completed COI Disclosure form has been completed for 2018 and it in the HR File.	B. Able	4/15/18	4/30/18	
4	ETC.								

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Compliance Program Administration

Measuring the effectiveness of program administration:

- ❑Reporting structure & access to senior leadership
- ❑Access to governing body
- ❑Staffing/budget
  - Qualifications and continuing education for staff
  - Program administration costs
  - Outside consulting/auditing budgets
- ❑Compliance committees & liaisons
- ❑Open lines of communication

Resource guide pages 8-16.

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Compliance Program Administration

- ❑Do you have access to your senior leadership team and governing body?
- ❑Do you educate your governing body regarding their role in compliance oversight and the value it provides to the organization?
- ❑Do you educate your senior management about their compliance responsibilities?
- ❑Staffing/budget
  - Do you align staffing with identified risks? Consider consulting or vendor dollars for risks that do not demand ongoing internal staffing?
  - Consider communication when budgeting – what do you need to communicate effectively in the organization?
  - Make the case for compliance staff continuing education and networking
- ❑Do you have a compliance committee & liaison structure that aligns with your key organizational risks?
- ❑How do you assess/measure your organization's culture of compliance?

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Committee Charters & Meeting Agendas

- ❑Charter Templates
  - Purpose – Be specific! What do you really want the Committee Members to do? What are they willing to do?
  - Duties and Responsibilities – use Action Verbs: Evaluate, Define, Establish, Assure, Review, Recommend, Impose
  - Composition and Meetings – Who, What, Where, When, and Why
  - Reporting structure, i.e., to BOD, to Compliance Committee
- ❑Gain charter approval – during approval explain importance of the charter to the overall compliance program objectives
- ❑Include a copy of the charter in meeting invites/agendas – helps build accountability among members

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Open Lines of Communication

- ❑Making good use of each and every contact and reporting opportunity
- ❑Reliability builds credibility
- ❑Know your audience
  - Don't lose them with too much detail!
  - Before you begin – know your goal
- ❑Educate as you go
  - Provide context
  - Progressive inclusion of content and detail
  - Check back in frequently
- ❑Be consistent
  - Standard reporting formats for executive and board committee reports
  - Use templates for minutes and activity trackers

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Screening and Evaluation of Employees, Physicians, Vendors and other Agents

Measuring the effectiveness of screening and evaluation:

- ❑Accountability for screening
  - Conflicts of interest
  - Exclusion screening
  - License/certification screening
- ❑Response to identified screening failure
- ❑Exit interviews

Resource guide pages 16-23.

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Screening Effectiveness

- ❑Do you have a conflict of interest policy?
- ❑Do you require a new hire/annual conflict of interest disclosure?
  - Who is required to complete this?
  - Who is responsible for documenting the results and actions taken?
  - Do you audit or refer back to conflict of interest disclosures during the year?
- ❑How is exclusion screening conducted (e.g., centralized in compliance, conducted by a vendor, or carried out in various areas such as human resources, medical staff, vendor management/contracting)?
  - Frequency?
  - What process exists if an excluded individual is identified?
- ❑Do you audit your exclusion screening documentation?
- ❑Does compliance have a role in auditing licensure/certification requirements of licensed staff?

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Exit Interviews

- ❑Does the organization conduct exit interviews?
  - Routine?
  - Only for high risk employees?
  - Vendors?
- ❑Who conducts the interviews(e.g., human resources, compliance, external firm)?
  - What is the information feedback loop to compliance?
  - If an employee declines an exit interview, is this communicated to compliance?

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Communication, Education, and Training on Compliance Issues

Measuring the effectiveness of communication and education:

- ❑New hire and annual training plan
- ❑Governing body training
- ❑Compliance communication plan
- ❑Processes to educate and implement new laws and regulations

Resource guide pages 23-31.

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Compliance Training

- ❑Does the compliance department maintain a training policy or training schedule?
- ❑Do all employees receive compliance training at hire? Annually?
  - How is the training developed – Mode of delivery? Attention to adult learning principles?
  - Is comprehension tested? Can staff provide feedback on training presentation?
  - Do all staff clearly learn how to report a compliance issue?
  - Is the culture of non-retaliation for reporting stressed during training?
  - How is training tracked?
- ❑What additional content-specific training is provided to "high risk" departments or job roles?
- ❑Does the compliance department leverage live training when available (creating a "compliance presence" throughout the organization)?
- ❑How is governing body training conducted? How is content determined?
- ❑How do vendors (FDRs) receive compliance training? How is content determined?
- ❑How is compliance training documentation maintained?

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Compliance Communications

- ❑Do you create an annual compliance communication plan?
  - Audiences to consider: organization wide, leadership, targeted high-risk staff
  - How do you assess the appropriateness of the communication content for the audience?
  - Do you use a variety of communication modalities?
  - How is accountability established for completing the plan?
- ❑Do you ask for/receive marketing support with internal communications?
- ❑Do you maintain a compliance department intranet page?
- ❑How does compliance staff maintain an organizational presence?

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Processes for implementing new laws/regulations

- ❑Who in the organization is responsible for tracking new laws/regulations? Is there a centralized intake process?
- ❑How are stakeholders convened to understand multidisciplinary impacts of new laws/regulations?
- ❑Who monitors implementation of new laws/regulations?
- ❑How are overdue regulatory implementations reported to leadership?

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Monitoring, Auditing, and Internal Reporting Systems

Measuring effectiveness of monitoring, auditing and internal reporting systems:

- ❑Internal Reporting System
  - Promotion
  - Access
  - Confidentiality
  - Response/investigation
    - Timeliness
    - Thoroughness
    - Action/follow-through
- ❑Monitoring and Auditing Work Plan
  - Communication of plan
  - Monitoring process & resources
  - Audit process & resources
  - Adherence to plan (completion rate)
- ❑Corrective Actions

Resource guide pages 31-29.

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Internal Reporting Systems

- ❑How can staff/community individuals report concerns?
  - How do you build awareness for how to report concerns?
  - How is your compliance hotline staffed?
  - How do you present the opportunity to report anonymously?
  - How do you assess whether employees trust the reporting system?
- ❑How are reported concerns tasked to appropriate investigators?
- ❑How do you track timeliness of response to reported concerns?
- ❑Do you report hotline volumes and category of concerns to your executive compliance committee and governing body?
- ❑Do you maintain documentation of all reported concerns?

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Monitoring and Auditing Work Plan

- ❑What is your process for developing monitoring and auditing plans based upon risk assessment results?
  - Do you have an organizational understanding of operational monitoring activities and feedback loops to compliance?
  - Are all audits conducted by individuals with appropriate independence?
- ❑How are work plans approved?
- ❑What work plan reporting occurs during the year?
- ❑How is the audit process conducted?
  - Does each audit begin with identifying purpose, scope, sample?
  - Who is accountable for participating in the audit process?
  - Do audit reports have a consistent format including findings, conclusion and recommendations?
- ❑Are audit results tracked/trended?
- ❑Who received notice of audit results?

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Corrective Actions

- ❑What is the process for conducting root cause analysis before developing corrective action plan?
- ❑How is accountability established for developing corrective action plans?
- ❑How is the corrective action plan assessed or approved?
- ❑How is timeliness of corrective action plan completion tracked/reported?

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Discipline for Non-Compliance

Measuring effectiveness of discipline for non-compliance:

- ❑Fairness and consistency of discipline
- ❑Awareness of non-compliance as a basis for discipline
- ❑Documentation & reporting of non-compliance based discipline

Resource guide pages 40-43.

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Compliance as an expectation of employment

- ❑How do you build relationships with human resources?
  - Training, tip sheets/guidelines, etc.
  - Do you schedule regular meetings to discuss issues pertinent to both groups?
- ❑Do all training materials stress compliance as an expectation of employment?
  - Is it included in job descriptions?
  - Is it included in performance evaluations?
- ❑How are staff made aware of compliance's role in ensuring the fairness and consistent application of human resource processes, including non-retaliation policies and obligations of management?
- ❑Do you track the number of disciplinary actions taken for non-compliance and the nature of the violation?

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Investigations and Remedial Measures

Measuring effectiveness of investigations and remedial measures:

- ❑Investigation process
  - Written investigation policy
  - Quality and consistency of investigations
  - Competency and independence of investigators
  - Documentation/content of files
  - Accountability for completing investigations and initiating corrective action
- ❑Reporting investigation outcomes
- ❑Corrective action plans/Remedial measures

Resource guide pages 44-53.

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Investigation Processes

- ❑Is there a policy to drive the process?
  - What is your definition of "investigation"?
  - How do you effectively use investigation resources to maximize risk identification/prioritization?
  - Does compliance have the authority to take immediate steps during the investigation (i.e., stop billing)?
- ❑Who are your investigators? Compliance? HR? Business?
- ❑Is the process transparent?
  - When do you communicate back to the initial reporter?
  - When do you invoke attorney-client privilege?
  - What criteria/triggers do you use to signal the use for outside resources (consultants, attorneys) and reporting to executives/board?
- ❑How are investigations documented?
- ❑Is there a central documentation repository?
- ❑How to you ensure timely completion of investigations?
- ❑Do you monitor investigations (QA activities) to ensure adherence to the policy?

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Reporting Investigation Outcomes

- ❑How are investigation outcomes communicated?
- ❑Consider including a "stakeholder" section in your investigation documentation and using this to address communication needs at the conclusion of the investigation.
- ❑Do you maintain meeting minutes of executive compliance committee that includes notation of closed investigations and corrective actions?
- ❑Do you report on timeliness of investigation closure?
- ❑Do you report aggregated data regarding the nature of the investigation (e.g., billing, code of conduct)

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Corrective Action

- ❑Does your investigation policy align with the 60-day overpayment rule and corrective action timeliness required to meet this rule?
- ❑How to do you establish accountability and timelines for corrective action completion?
- ❑How do you measure the sufficiency of corrective action plans that are developed?
- ❑How are corrective action plan progress/completion reported to key stakeholders?

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Effective Communication and Compliance Culture

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10 Traits of a Good CCO

- ❑Integrity
- ❑Courage
- ❑Presence
- ❑Strong Analytical Ability & Understanding of Laws and Regulations
- ❑Attention to detail and global vision
- ❑Leadership
- ❑Business Acumen
- ❑Teamwork
- ❑Proactivity
- ❑Reactivity

Source: 10 Traits of a Good CCO: Lessons From Polar Exploration. Accessed at: https://www.law.com/almID/528b5ba8140ba00d190000035/

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Communication – CCO and Beyond

- Tone at the Top
  - What message comes from the Governing Body?
  - How about the CEO and Senior Leadership?
  - Is leading by example prominent throughout leadership/management?
- Ways to measure communication effectiveness:
  - Surveys
  - Interviews with staff/stakeholders
  - Exit Interviews

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Risk Assessment and Risk Management

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Regulations and Guidance

- Medicare Medicare Advantage - Prescription Drug (MA-PD) Plan and Medicare-Medicare Plan (MMP) require the Managed Care Organization to implement an effective system for routine monitoring and identification of compliance risks. (Medicare Managed Care Manual, Chapter 21, Section
- Office of Civil Rights (HIPAA) Security Rules controls require covered entities to have both Security Management Process – Risk Analysis and a Security Management Process for Risk Management
- Office of Inspector General (OIG) Compliance Program Guidelines
- US Federal Sentencing Guidelines (e.g., guiding principles of an effective Compliance Program

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Identifying Risks – Many Places

- ❑Interviews from Stakeholders (e.g. leadership, business owners)
- ❑Current Compliance Data
  - Past Regulatory Actions
  - Internal and External Audits
  - Corrective Action Plans within the past 12 months
  - Emerging Risks in the Marketplace
  - Industry Trends/OIG Work Plan
  - New Regulatory Requirements
- ❑Other Sources, i.e., the News!
- ❑Independent, External Mock Audits of Organization
- ❑Develop Risk Inventory from Input Above

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Prioritizing Your Risk Inventory

- ❑Business Owners rank risks in their areas
  - Experience
  - Knowledge
- ❑Review
  - Likelihood of occurrence – High, Medium, Low or 1-5 Scale
  - Impact to the Organization – High, Medium, Low or 1-5 Scale
  - Velocity – Time to Impact
- ❑Evaluate results at Compliance Level
- ❑Calculate
  - Likelihood x Impact = Risk Score
  - Likelihood x Velocity x Impact = Risk Score
- ❑Risk Map – Plots areas of Risks

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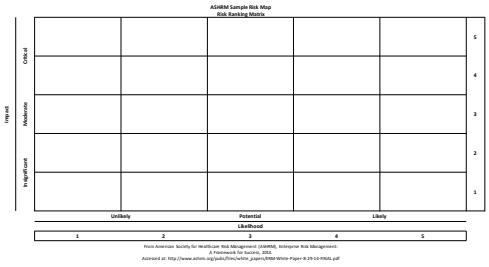
Risk Map – ASHRM



From American Society for Healthcare Risk Management (ASHRM), Enterprise Risk Management: A Framework for Success, 2014.
Accessed at: http://www.ashrm.org/pubs/files/white_papers/ERM-White-Paper-8-29-14-FINAL.pdf

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Risk Management – Next Step

- Develop a work plan to manage the identified risks.
  - Transfer
  - Mitigate/Reduce
  - Eliminate
  - Accept
- Work Plan must be detailed
  - Risk, Domain, Priority
  - Owner, Action
  - Start and Completion Date
  - Validation Completion Date
- The worst thing you can do it identify risks and not do anything about them. However with limited resources, risk prioritization and documentation of the prioritization process is critical.

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First Tier, Downstream, and Related Entities

"AKA" VENDOR MANAGEMENT

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Definitions from MMCM, Chapter 21, §20 and §40.

- **First Tier Entity** is any party that enters into a written arrangement, acceptable to CMS, with an MAO or Part D plan sponsor or applicant to provide administrative services or health care services to a Medicare eligible individual under the MA program or Part D program.
- **Downstream Entity** is any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the MA benefit or Part D benefit, below the level of the arrangement between an MAO or applicant or a Part D plan sponsor or applicant and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.
- **Related Entity** means any entity that is related to an MAO or Part D sponsor by common ownership or control and
  - Performs some of the MAO or Part D plan sponsor's management functions under contract or delegation;
  - Furnishes services to Medicare enrollees under an oral or written agreement; or
  - Leases real property or sells materials to the MAO or Part D plan sponsor at a cost of more than $2,500 during a contract period.

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Delegated Function Examples

- ❑ Sales and marketing
- ❑ Utilization management
- ❑ Quality improvement
- ❑ Applications processing
- ❑ Enrollment, disenrollment, membership functions
- ❑ Claims administration, processing and coverage adjudication
- ❑ Pharmacy benefit management
- ❑ Hotline operations
- ❑ Customer service
- ❑ Bid preparation
- ❑ Credentialing and Provider network management

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Identification Process

❑Do you know who your FDRs are?

- Is there a centralized location for all contracting?
- Do you use questionnaires to assist Business Owners identify them?
- Do vendors go through a purchasing and procurement process.
- Is the vendor performing a delegated Medicare function.
- Other?

Once you delegate a function you are required to do by contract, you have an FDR or First Tier Entity relationship.

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Audit & Monitor

CMS requires Sponsors to develop procedures to promote and ensure that all FDRs are in compliance with Medicare regulations. And, have a system in place to monitor FDRs.

❑Do you have a documented auditing and monitoring plan to provide oversight?

❑Do you evaluate your FDRs performance with standard metrics?

❑Do you Audit & Monitor all First Tier Entities? If not, how do you determine who gets what type of oversight?

❑Does the delegated entity:

- Touch a member's life directly through service delivery or other face-to-face interaction?
- Receive, create or maintain PHI?
- Have decision-making authority?
- Ability to harm members and/or Commit Fraud, Waste, and Abuse?
- Other Factors: Outstanding CAPS, Significant Deficiencies, New FTE, etc.

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FTE Delegated Function Grid

FTE Name	Delegated Function	Face to Face Member Impact	Some Member contact	Access to PHI	Decision-Making Authority	Potential Harm to Member	Potential to commit FWA	Open CAPs	New FTE	Risk Score	Risk Level	Audit Type
A	PBM	Y	Y	Y	Y	Y	Y	N	N	12	H	Full
B	Bid Prep	N	Y	N	N	N	N	N	Y	4	L	Attestation
C	Claims Process (with CS)	N	Y	Y	Y	N	Y	N	N	8	M	Monitor
D	Shredder Company	N	N	N	N	N	N	N	N	0	L	Attestation

Legend	Y = 2
	N = 0

Risk Ranking	0-5	Low
	6-10	Medium
	11-16	High

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Other FDR Requirements

- ❑Do you provide FDRs with training materials?
- ❑Do you validate your FDRs against the exclusion lists?
- ❑Do you review the specific FDR P&Ps which support your business? Annually?
- ❑Do you educate FDRs on how to report a issue or concern?
- ❑Do you verify that FDRs are overseeing their Downstream Entities and Related Entities in a similar manner?

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The Relationship Between Compliance and Information Privacy & Security

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Effectiveness of Information Privacy/Security Program

- If your compliance program scope includes oversight of information privacy/security, these risks should be included in overall compliance program activities.
- If your compliance program scope does not include information/privacy security, how do you coordinate with the leaders responsible for these programs to ensure a similar approach to measuring the effectiveness of these programs?
  - Include these in your risk assessment
  - Allocate audit resources to assess the privacy/security program activities
  - Regular communication with these leaders/staff
  - Develop written processes regarding reported concern investigations and documentation of investigation findings

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Top Takeaways

- Prioritize your risks
  - Every program has limited resources; so effectiveness demand diligent attention to risk prioritization
  - Acknowledge that new risks always arise, and re-prioritization must occur
  - Don't ignore small risks – but keep a parking lot list (involve your staff)
  - Strive to right-size your "risks" with your "resources"
- Trust, but verify!
  - Verification forms the basis of measuring effectiveness
  - Perform validation testing to see if the reported CAP, system change, P&P update, etc. has been implemented and is true and accurate.
- Communications is the Key to Success and Effectiveness!
  - Know your audience and stick to the point
  - Use the 10 Traits of a Good CCO as your guide

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Conclusion

- The Measuring Compliance Program Effectiveness: A Resource Guide has over 400 suggestions that you may use for your Compliance Program.
- We reviewed about 10% of what was in the Resource Guide!
- Remember, **"One Size, Does NOT Fit All!"**
- You have an opportunity to establish your vision and, ultimately, create your own program to measure effectiveness of your Compliance Program based upon the type, size, organizational structure, and footprint of your organization.
- Good luck!

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Thank you!

Questions?

Thank you!

Questions?

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