



FDR OVERSIGHT - What can you to do to provide FDR oversight?

**HCCA New York Regional Compliance
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Overview

- Regulations and Guidance
- Contracting
- Risk Assessment & Management
- Auditing & Monitoring
- Tools
- Common Findings / Improvements
- Case Study – SynerMed
- Top Takeaways!



Regulations and Guidance

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 40.)

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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.



Contracting

- Define your expectations:
 - Performance Standards (KPIs, SLAs etc.)
 - Performance Guarantees
 - Data sharing
 - Privacy and Security

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Contracting

- Reporting and Audit:
 - Operational reporting content and frequency
 - Regulatory submissions
 - Preparation of universes
 - Development, QA and error resolution (the devil is in the details)

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Contracting

- Systems and software:
 - Outage, error resolution, escalation, SDLC.
- Regulatory changes
 - Review, action and software changes
- CMPs and other government penalties
- CAP turn around and exit strategy

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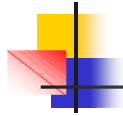
Risk Assessment - Actions

- 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

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Risk Assessment - Actions

- 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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Risk Management - Prioritizing

- 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

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Risk Management - Prioritizing

- 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

ASHRM Sample Risk Map
Risk Ranking Matrix

Impact	Critical	5	4	3	2	1
	Moderate	4	3	2	1	5
	Insignificant	3	2	1	5	4
		2	1	5	4	3
		1	5	4	3	2
		Unlikely	Potential	Likely		
		Likelihood			1	5

From American Society for Healthcare Risk Management (ASHRM), Enterprise Risk Management: A Framework for Success, 2014.
 Accessed at: http://www.ashrm.org/pub/Files/white_paper/ERM_White_Paper_8.29.14_FINAL.pdf

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Next Steps for Risk Mgt.

- Develop a work plan to manage the identified risks.
 - Transfer
 - Mitigate/Reduce
 - Eliminate
 - Accept

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Next Steps - continued

- Work Plan must be detailed
 - Risk, Domain, Priority
 - Owner, Action
 - Start and Completion Date
 - Validation Completion Date

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A Note of Caution

- The worst thing you can do is identify risks and not take action, unless you prioritized accordingly.
- With limited resources, risk prioritization and documentation of the prioritization process is critical.

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Auditing & Monitoring

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?

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Auditing & Monitoring

- 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?

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Auditing & Monitoring

- 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

Legend	Y = 2
	N = 0


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

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Auditing / Monitoring Tools

Audit Title	
Audit Period	
Conclusion: Requirement Met/Not Met	
Description of Requirement	
Scope	
Audit Procedures	
Findings	
Recommendations	
Corrective Action Requirements	
Responsible Party	
Implementation Date	

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Compliance Review Checklist
Check box when complete.

<p>Advanced Planning</p> <ul style="list-style-type: none"> <input type="checkbox"/> Identify compliance issue and define scope, including: <ul style="list-style-type: none"> <input type="checkbox"/> Time period to be reviewed <input type="checkbox"/> Exact concern or question to be answered <input type="checkbox"/> Identify to whom the findings will be presented, who: <ul style="list-style-type: none"> <input type="checkbox"/> Is independent from topic at issue <input type="checkbox"/> Has authority to take corrective action if needed <input type="checkbox"/> Decide whether the review will be conducted under the attorney-client privilege <input type="checkbox"/> Identify person to lead the review (consider each): <ul style="list-style-type: none"> <input type="checkbox"/> Leader has appropriate training and expertise <input type="checkbox"/> Leader has capacity and resources <input type="checkbox"/> Interview person making complaint to clarify concerns (if complaint-based) <input type="checkbox"/> Set out deadline for significant stages of the review <input type="checkbox"/> Create separate file and mark confidential <input type="checkbox"/> Add initiation of the review to compliance log <p>Fact Gathering – Documents and Data</p> <ul style="list-style-type: none"> <input type="checkbox"/> Consider need for “litigation hold/preservation notice” <input type="checkbox"/> Obtain documents from internal sources (consider each): <ul style="list-style-type: none"> <input type="checkbox"/> Relevant individuals or departments <input type="checkbox"/> Documents in central files or storage <input type="checkbox"/> Emails, shared drives or other electronic locations <input type="checkbox"/> Claims, remits, clinical documentation <input type="checkbox"/> Obtain external documents or data (e.g., FMV data, Medicare payment rates, vendor policies) or deem unnecessary <input type="checkbox"/> Consult internal experts or deem unnecessary <input type="checkbox"/> Consult outside experts or deem unnecessary <p>Fact Gathering – Witnesses and Experts</p> <ul style="list-style-type: none"> <input type="checkbox"/> Identify individuals with first-hand information (each “witness”) <input type="checkbox"/> Consider order of witness interviews <input type="checkbox"/> Draft list of questions for each witness <input type="checkbox"/> Interview witnesses <input type="checkbox"/> Summarize each interview in file <p>Identify standard, rule, or policy that applies</p> <ul style="list-style-type: none"> <input type="checkbox"/> Review company policies and procedures <input type="checkbox"/> Review applicable regulations or statutes <input type="checkbox"/> Review guidance from government agencies, coding rules, etc. <input type="checkbox"/> Determine whether legal or expert advice is necessary <input type="checkbox"/> Acknowledge ambiguities, if any <ul style="list-style-type: none"> <input type="checkbox"/> Draft timeline or deem unnecessary <input type="checkbox"/> Identify undisputed or consistent facts <input type="checkbox"/> Identify and address conflicting testimony or data 	<p>Analyze Core Compliance Concerns</p> <ul style="list-style-type: none"> <input type="checkbox"/> Medicare/Medicaid overpayments (pick one): <ul style="list-style-type: none"> <input type="checkbox"/> None <input type="checkbox"/> Identify overpayments and refund <input type="checkbox"/> Duty to report to government agency (pick one): <ul style="list-style-type: none"> <input type="checkbox"/> No duty to report <input type="checkbox"/> Potential duty to report: Refer to General Counsel <input type="checkbox"/> Other material compliance risks (pick one): <ul style="list-style-type: none"> <input type="checkbox"/> None <input type="checkbox"/> Significant legal, financial, or reputation risk to organization: Refer to General Counsel <input type="checkbox"/> Conclusions indicate existence of larger compliance or operational issue <input type="checkbox"/> Deviation from standard of care or potential patient harm <p>Draft Report</p> <ul style="list-style-type: none"> <input type="checkbox"/> Prepare written document, even if brief or only for the file, that includes (consider each): <ul style="list-style-type: none"> <input type="checkbox"/> Executive summary <input type="checkbox"/> Compliance issue reviewed <input type="checkbox"/> Efforts to gather and sources of information <input type="checkbox"/> Relevant standard, rule, or policy <input type="checkbox"/> Timeline or outline of key events <input type="checkbox"/> Factual and overall conclusions <input type="checkbox"/> Recommendations for remediation or other next steps <p>Implement Prospective Action</p> <ul style="list-style-type: none"> <input type="checkbox"/> Identify basis for non-compliance and most appropriate strategy for preventing similar non-compliance in the future <input type="checkbox"/> Update policies or deem unnecessary <input type="checkbox"/> Complete education and training or deem unnecessary <input type="checkbox"/> Take HR corrective action or deem unnecessary <input type="checkbox"/> Plan for future audit to ensure that corrective measures were effective or deem unnecessary <input type="checkbox"/> Document all corrective actions taken <p>Closure</p> <ul style="list-style-type: none"> <input type="checkbox"/> Present findings to appropriate party/committee <input type="checkbox"/> Compliance Officer closes the loop with: <ul style="list-style-type: none"> <input type="checkbox"/> Person who raised the issue <input type="checkbox"/> Significant witnesses <input type="checkbox"/> Senior leadership (as needed) <input type="checkbox"/> Organize and file documents <input type="checkbox"/> Update compliance log: Review concluded
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Auditing / Monitoring Tools



Standard	Documents/Policies Reviewed	Standard Met	Findings
		Yes/ No/ NA	
III) Sample of credentialing files and documentation (20 provider (P) and 20 facility (F) files). 95% of the completed credentialing and re-credentialing files contain:	Credentialing files and documentation.		
a. Correctly completed application (P)(F)			
b. Current credentialing (no more than 6 months from appointment date – initial, no more than 3 years old – recredentialing), (P) (F)			
c. License. (P) Operating Certificate (F)			
d. Board Certification.(P)			
e. Education (Board uses primary source) (P)			
f. Clinical Privileges. (P)			
g. Malpractice Insurance. (P)			
h. DEA or CDS Certificate. (P)			
i. NPDB. (P)			
j. Quality of Care issues. (P) (F)			
k. Exclusion Checks (OIG, OMIG, LEIE, SAM). (P) (F)			
l. Medicare Opt Out List/ NPI (P) (F)			

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Auditing / Monitoring Tools

Function	Plan	Indicator	Targets	YTD Average	Jan	Feb	March	April	May	June	July	August
Enrollment	MAPD (001)	Enrollment Transactions submitted to CMS within 7 days of receipt of Form	100%	96%	90%	90%	93%	97%	96%	98%	100%	100%
	MAPD (001)	Confirmation Notice Sent within 10 days of TRR	100%	95%	96%	97%	95%	98%	99%	87%	87%	99%
	MAPD (001)	ID Card mailed within 10 days of TRR	100%	100%	98%	99%	100%	100%	100%	100%	100%	100%
	MAPD (001)	EOC/Directory Notice mailed within 10 days of TRR	100%	90%	80%	80%	90%	89%	90%	93%	95%	99%

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Commons Findings – Sponsors Did Not:

- Follow-up on previous audit findings to ensure that issues were resolved
- Provide FWA Training or FWA materials to FDRs or have evidence
- Check the OIG and GSA Exclusion List
- Establish/implement effective systems for A&M as well as oversight mechanisms
- Institute communications lines
- Effective process to identify risks.

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Why?

Sponsors did not:

- Have process to ensure FDRs were identified as requiring training at contracting and annually thereafter.
- Have sufficient resources to implement an effective compliance program.
- Know these items were Medicare requirements.

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Improvement Strategies

- Communication
- Automate Sanction Screening process
- Use CMS Compliance & FWA Training
- Develop robust FDR A&M program
- Validate CAPs have been implemented

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SynerMed – In the News

By CHAD TERHUNE | KAISER HEALTH NEWS | NOV 15, 2017 | 10:40 AM

“Company that runs physician practices is closing down amid heightened scrutiny!”

- In an internal email, the CEO of SynerMed said audits by health plans found “several system and control failures.”
- As a result, the company "will begin the legal and operational steps to shut down all operations."

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Some Facts

- 8/18/17 – HealhtNet Audit of SynerMed
- 9/1/17 – Compliance materials
- 9/7/17 – Audit files requested; due 9/15/17
- 9/15/17 – Extension requested to 9/25/17
- 9/25/17 – Missing some denial files
- 9/27/17 – Delegated Oversight Coordinator informs Compliance delay due to staff falsifying letters and faxes to pass audit.

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Facts continued

- 9/27/17 to 10/4/17 – Investigation
- Sr. Management not responding to Compliance
- 10/4/17 – Sr. Compliance Director feeling threatened but will continue to fight
- Report of Findings, dated 10/5/17, is sent internally and, a few days later to CA regulators. (Date sent unknown.)

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Findings

Significant Non-compliance with provider and member denial notifications and falsified documents to pass audits.

- Provider/Members unaware of ODAG
- No appeal rights
- Non-clinical staff writing clinical rationale; Staff signing MD name
- Member harm; potential delay in care and financial hardship

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Top Takeaways!

- Identify your FDRs!
- Prioritize your Risks!
- Trust but Verify!

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Thank You!

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