FDR Oversight

HALL RENDER
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The Who, Why, and How

FDR Oversight

- **FDR** means First Tier, Downstream or Related Entity
- **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. (See, 42 C.F.R. § 423.501).
- **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. (See, 42 C.F.R. § , 423.501).

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- **Related Entity** means any entity that is related to an MAO or Part D sponsor by common ownership or control and
- (1) Performs some of the MAO or Part D plan sponsor's management functions under contract or delegation;

- (2) Furnishes services to Medicare enrollees under an oral or written agreement; or

- (3) 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. (See, 42 C.F.R. § 423.501).

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- **Real life examples:**
  - **First Tier Entities:**
    - PHOs
    - Enrollment Verification Companies
  - **Downstream Entities:**
    - Credentialing Verification Units (CVUs)
    - Contracted Providers
  - **Related Entities:**
    - Commonly Owned PBM
    - Commonly Owned Call Center

Examples

Entity Description	Type	Delegated Functions								
		Claims Processing	Utilization Management	Pharmacy Coverage Determinations	Credentialing	Call Center Operations	Provider/Facility Contracting	Member/ Marketing Material	Part C Appeals and Grievances	Part D Appeals and Grievances
ABC Prescriptions	PBM	X		X	X		X			X
Mail R Us	Member Notices & Materials							X		
Orthopedics USA	Prostethics and Orthotics	X	X		X	X				
XYZ Company	Outbound Enrollment Verification					X				
QRS, Inc.	OIG/GSA exclusion lists verification									
Market 4 You, Inc.	FMO				X			X		

5

FDR Oversight

- **Why oversee them?**
  - According to the CMS Managed Care Manual, "The MA organization agrees to take ultimate responsibility for all services provided and terms of the contract and otherwise fulfilling all terms and conditions of its contract with CMS regardless of any relationships that the organization may have with entities, contractors, subcontractors, first-tier or downstream entities."

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- **So, how do we do it?**
  - **Monitoring and Auditing Plans**
    - **Monitoring**: Regular reviews performed as part of normal operations, to confirm ongoing compliance (e.g. via delegated oversight committee, regular reporting, etc.)

    - **Auditing**: Formal reviews of compliance, with particular set of standards as base measures, using a compliance risk assessment tool that evaluates risk levels (e.g. red, **yellow**, green; high, medium, low)

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- **Why is monitoring and auditing important?**
  - **Avoid FWA (Fraud, Waste, and Abuse)**
    - **Fraud**: Knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program

    - **Waste**: Practices that, directly or indirectly, result in unnecessary costs to the Medicare Program

    - **Abuse**: Actions that may, directly or indirectly, result in unnecessary costs to the Medicare Program such as paying for items or services when there is no legal entitlement

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- **How do you avoid FWA?**
  - **FWA (Fraud, Waste, and Abuse)**
    - **FWA**: Use of data analysis to identify unusual patterns which suggest potential errors and/or potential fraud and abuse
    - **Data Analysis**: Analyze claims data to identify potential errors and provider billing practices and services that poses the greatest risk for potential FWA to the Medicare program
    - **Policies and Procedures**: Effective program to identify and address FWA at both the Sponsor and FDR levels

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- **How do you avoid FWA (continued)?**
  - **Special Investigation Units (SIUs)**
    - **SIU**: Internal investigation unit responsible for conducting surveillance, interviews and other methods of investigation relating to potential FWA
    - **Responsibilities of SIU**: Reduce or eliminate Medicare Part C/D benefit costs due to FWA; Reduce or eliminate fraudulent or abusive claims paid for with federal dollars; Prevent illegal activities

FDR Oversight

Seven Steps for Success

1. Develop Governance Structure & Program Objectives
2. Assign Roles and Responsibilities
3. Inventory Vendors and Identify FDRS
4. Perform Risk Assessments
5. Prepare and Determine Methodology
6. Evaluate and Audit
7. Report Results and Ongoing Monitoring
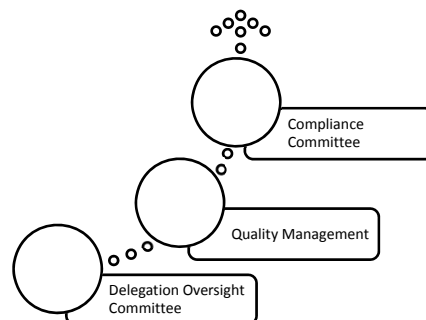
12

Oversight Objectives

- Ensures that proper internal controls are in place to monitor FDRs on a routine basis

- Review FDR performance to ensure compliance with:
  - Contractual provisions
  - Policies and procedures
  - CMS requirements, applicable state and federal regulatory requirements
  - Accreditation standards
  - Oversight of downstream entities used by FDR

- Provides management with reasonable assurance that delegates are delivering quality services on behalf of the organization

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13
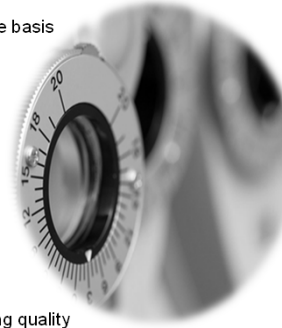
Governance Structure

Develop a governance structure comprised of key stakeholders charged with the following:

- Provide subject matter expertise
- Ensure controls are in place to identify, review and monitor FDR compliance
- Review risk assessments results and prioritize FDRs for audit
- Review audit results and approve audit team recommendations for corrective action

Compliance Committee

Quality Management

Delegation Oversight Committee

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14

Sample Delegation Oversight Committee Membership

Director, Contracting
Director, Privacy
Director, Procurement
Chief Compliance Officer
Director, Audit
Chief Information Security Officer
VP, Operations
VP, Medical Management
Director, Customer Service
Director, Claims

Director, Regulatory Affairs
Director, Compliance
Director, Network Operations

	Shared Services	Clinical/Operations
	Compliance/Audit	Executive
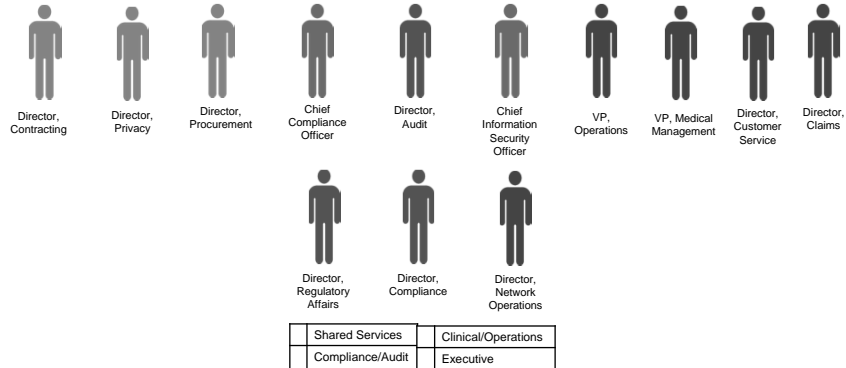
Define Roles and Responsibilities

ROLE	RESPONSIBILITY
Committee	Approve recommendations, assist with prioritization, review audit results and decide on action
Audit Team	Develop tool, conduct audit, summarize results, make recommendations to oversight committee
Business Owner	Provide functional standards and requirements, assist in development of tool, participate in on sight audit as needed
Other SMEs	IT-Perform audit on technical safeguards

Relationship Owners

Audit Team

Delegation Oversight Committee
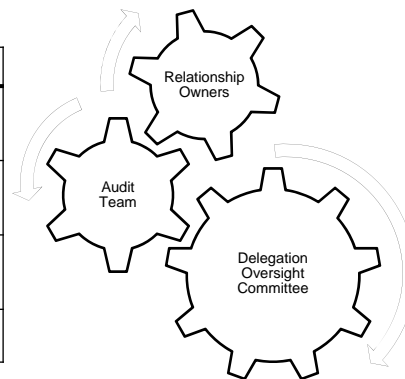
Defining Delegation

- Regardless of the definition, the organization h is ultimately held responsible.
  - The organization may give a delegate the authority to perform functions on its behalf, but remains accountable.
  - If the function was not performed by the delegate, would there be a need for the organization perform the function to operate.
- Outsourcing functions is not simply delegating a task to a vendor; they share the organization's culture, mission and values.

Vendor	FDR
	Delegated administrative or health care service functions relating to the Medicare contract
Provided Service	Provide Service
Compensated for service	Compensated for service

17
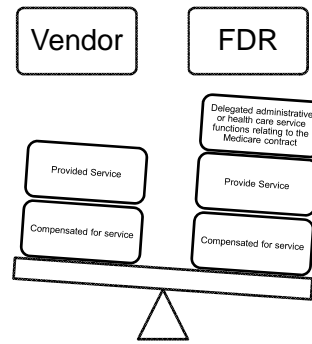
Inventory and Assessment of Vendors

- Start and then filter based on defined definition of delegate

- Develop a set of risk factors

- Score vendors

- Review with oversight committee

- Prioritize review based on risk review

Sample Risk Assessment Model
Twelve (12) risk factors evaluated for each in-scope delegate
• Responses weighted on a scale of 0-10 depending on significance
• Example Risk Factors Considered: Lines of business managed by vendor, PHI, population size, level of member contact, services and relationship to organizational risk areas, regulatory risk

| Risk Ranking	Overall Score
High	20 – 55
Medium	10 – 19
Low	0 – 9

18

Sample Planning and Proposed Timeline

New Audits require approximately three and a half months to complete

– Month one: Planning (review contract, creation of audit tool and scope development)

– Month two: Vendor responds to desk top portion of audit and document requests

– Month three and a half: Conclude (test support, follow-up time, and compile results)

	May	June	July	August	September	October	November	December
Review 1								
Review 2								
Review 3								
Review 4 (Aperture)								
Review 5								

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Preparation and Methodology
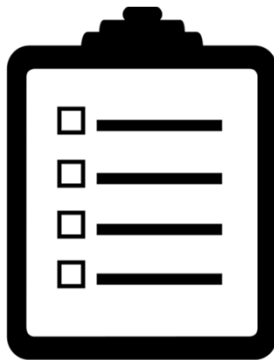
Considerations for developing audit scope and tools:

- Review contract with Business Owners
- Determine scope of oversight
  -Technical, security or functional
- Type of audit performed
    -onsite or desktop
    -technical, security or functional
- Draft Scoping Letter
- Draft audit tools with help from Business Owners

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Evaluate and Audit

> Audits should include a mix of both desktop and on-sight review
> Ensure that FDR has a appropriate amount of time to prepare
> Incorporate face to face discussions with document and file reviews
> Timely communication around findings and issues is critical
> Set clear expectations around successful performance (Pass/Fail versus threshold score requirements)
> Closing meetings are helpful in addressing initial findings quickly
> Final report will be an iterative process with

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21

Process Summary

COMMITTEE FORMATION	ROLES	VENDOR LISTING	RISK ASSESSMENT	PREPARATION	AUDIT	REPORT & MONITOR
Charter and introduction of committee to organization	Make accountability for oversight clear. Define roles and responsibilities internally	Starting broad will ensure that all vendors that are potentially in scope are identified. Use factors to filter out those that are not FDRs	Completed risk assessment for delegates deemed in-scope will help the organization prioritize especially if there are a large number of vendors in scope.	Core functions: Claims Processing, Utilization Review, Primary Source Verification, Clinical Outreach	Ensure that the audit is performed and results are produced timely. The sooner issues are identified the sooner they can be corrected	The annual audit is only a part of proper oversight. Monitor throughout the year.

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22

11