



PROVEN METHODS TO STREAMLINE & OPTIMIZE FDR OVERSIGHT

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The opinions and information provided during this presentation are that of the speakers and do not necessarily represent the opinions of their employer.

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Session Agenda

- FDR oversight and monitoring of often overlooked functional areas
- Pharmacy Benefits Manager (PBM) auditing & monitoring best practices

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Definitions

- **Vendor Management:** The business owners responsible for the implementation, operations, monitoring, and day-to-day relationship with the FDR/Subcontractor
- **Vendor Oversight:** Often times the Compliance Department, which is responsible for oversight of expected FDR/Subcontractor deliverables and metrics, and supporting of issues escalations and corrective actions
- **First Tier Entity:** A party that enters into a written arrangement with a Medicare Advantage Organization ("MAO") or Part D plan sponsor (Covered Entity) to provide:
 - *Administrative services (e.g., marketing, utilization management, care & disease management, network adequacy, quality assurance, applications processing, enrollment and disenrollment functions, claims processing, adjudicating Medicare organization determinations, appeals and grievances, provider credentialing); or*
 - *Health care services to a Medicare eligible individual under the Medicare Advantage program or Part D program (e.g., independent practice association, hospital, etc.)*

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Definitions

- **Downstream Entity:** A party that enters into a written arrangement with a First Tier entity for the provision of administrative services or health care services to a Medicare eligible individual under the Medicare Advantage program or Part D program
 - *Hospital within a health system that has entered into a system level agreement*
 - *Credentialing verification organization*
- **Related Entity:** Any party that is related to the Covered Entity by common ownership or control and either: (1) performs some of the sponsor's management of functions under a contract of delegation; (2) furnishes services to Medicare enrollees under an oral or written agreement; or (3) leases real property or sells materials to the sponsor at a cost of more than \$2,500 during a contract period
- **Pharmacy Benefit Managers (PBM):** PBMs are primarily responsible for developing and maintaining the formulary, contracting with pharmacies, negotiating discounts and rebates with drug manufacturers, and processing and paying prescription drug claims. PBMs can reduce prescription drug costs and improve convenience and safety for consumers, employers, and government programs

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FDR Compliance Oversight

- Covered Entities are ultimately responsible for actions delegated to first tier, downstream, and related (FDR) entities
- Entities must maintain adequate and effective oversight of the FDR & Vendors/Subcontractors to ensure that they comply with applicable contractual and regulatory requirements

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Evaluation of Core Services

- When evaluating entities for enrollment in your network its important to determining whether an entity is an FDR, for the purpose of exercising compliance and operational oversight
 - *Whether the entity performs a core service*
 - *Whether the function is a service the Covered Entity is required to do or provide under its contract with Medicare and applicable federal regulations or guidance*
 - *Whether the function directly impacts enrollees*
 - *Whether the entity has interaction with enrollees*
 - *Whether the entity has access to beneficiary information or personal health information*
 - *Whether the entity has decision-making authority*
 - *Whether the function places the entity in a position to commit health care fraud, waste or abuse*
 - *The risk that the entity could harm enrollees or violate Medicare and/or other regulatory program requirements*

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Pre-Delegation Assessment

- Prior to delegating a core service to an FDR, the Covered Entity should perform a pre-delegation assessment
 - *The review will cover topics such as the FDR's experience in the delegated area, its operational performance, policies and procedures, compliance program infrastructure and adherence, compliance monitoring and auditing, HIPAA Privacy and Security, record retention, and reportable metrics*
- In determining whether to conduct the review, the Covered Entity should assess the FDR's specific functions, the risks associated with the FDR, and the size and magnitude of the contract

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FDR Assessment & Core Services

- Once identified as an FDR, the Covered Entity shall exercise oversight of the FDRs who performs a delegated, core service on behalf of the organization

<ul style="list-style-type: none"> • Sales and marketing • Health care services • Utilization management <ul style="list-style-type: none"> • Quality improvement • Enrollment, disenrollment, membership functions <ul style="list-style-type: none"> • Outbound enrollment verification • Applications processing • Claims administration, processing and coverage adjudication • Generation of claims data 	<ul style="list-style-type: none"> • Pharmacy benefit management (PBM) <ul style="list-style-type: none"> • Processing of pharmacy claims at the point of sale • Administration and tracking of enrollees' drug benefits • Negotiation with prescription drug manufacturers and others for rebates, discounts or other price concessions on prescription drugs • Care/Disease Management 	<ul style="list-style-type: none"> • Appeals and grievances • Hotline/Call Center operations • Customer service • Provider network management <ul style="list-style-type: none"> • Licensing and credentialing • Network adequacy analysis • Coordination with other benefit programs such as Medicaid, state pharmaceutical assistance or other insurance programs
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Compliance Program Dissemination

- Within **90 days** of contracting, and on an annual basis thereafter, the Covered Entity, should distribute its Compliance Program and Standards of Conduct to all applicable FDRs
- The FDR should be required to sign an acknowledgment of receipt and an attestation of understanding of the Entity's Compliance Program and Standards of Conduct

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FDR/Subcontractor Compliance Program

- Covered Entities should require certain high-risk FDRs to maintain their own effective compliance program consisting of the 7 core elements
- Vendor Oversight and the Compliance Department must (based on a risk assessment) review the FDR's compliance program at the time of contracting, and annually thereafter
- Entities should require the FDR to provide a signed attestation / certification of their compliance with this requirement, subject to validation

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Laws & Training

- FDRs must comply with applicable laws and regulations that pertain to government programs, such as HIPAA, Federal False Claims Act, and CMS guidelines
- FDRs must administer effective training and education to all employees who are responsible for the administration or delivery of government programs at the time of hire and annually thereafter
- Training and education must cover general compliance standards, regulatory requirements, as well as contractual requirements for delegated services

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Compliance Investigation & Reporting

- FDRs are expected to disclose to Covered Entities potential issues of noncompliance and FWA in a timely manner.
- FDRs are also expected to cooperate with Covered Entities in the investigation and resolution of such issues. Upon discovery of an incident or report of a potential noncompliant or FWA issue, the FDR is expected to initiate a thorough investigation of the incident.
- In addition, the FDR must maintain effective lines of communication within its organization to ensure that its employees understand their obligation to raise compliance issues, and provide a means for anonymous and confidential good faith reporting of potential compliance issues as they are identified.
- Lastly, the FDR must support a non-intimidation and non-retaliation environment that allows individuals to make good faith reports without repercussion or fear of retaliation.

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Disciplinary Standards

- FDRs must maintain disciplinary standards to ensure that employees who commit a compliance or FWA violation are subject to disciplinary and corrective actions, up to and including termination
- Documented disciplinary standards help to ensure individuals are treated equally based on the violation
 - *Tiering of discipline standards and levels of violation*

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Monitoring & Auditing

- Covered Entities must require applicable FDRs to conduct self-monitoring and self-auditing of their operational performance, remedy all identified areas of deficiency, and disclose them
- In addition, Vendor Management is obligated to oversee and routinely monitor the FDRs daily work performance and compliance relative to its delegated functions
- Vendor Oversight must routinely monitor and assess the FDRs operational performance as it relates to compliance measures

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General Oversight – Performance Metrics

- FDRs are required to provide and report on appropriate operational performance metrics that reflect the FDR's compliance with regulatory standards and contractual obligations
- FDRs are expected to maintain regular operational or management meetings with the Covered Entity as appropriate, to ensure issue resolution, process enhancements, and coordinated & consistent communication

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General Oversight - Post Implementation

- Vendor Oversight should conduct a post- implementation audit approximately **60 - 90 days** after the initial go-live date and annually thereafter
- This is done to ensure that the FDR is performing in accordance with State, Federal and Entity standards and business expectations, and that issues are identified and remediated early in the contract relationship

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Understand Your FDRs

- Begin by verifying the organization has consistent and appropriate criteria used to identify an FDR. Not all vendors or subcontractors are FDRs. To be an FDR, the entity must provide administrative or health care services to a Medicare beneficiary
- Next determine if the appropriate contractual agreements are in place. For example, a Covered Entity need a Business Associate Agreement (BAA) with each First Tier entity. In addition, there are regulatory requirements that must be included in every contract between a Covered Entity and a First Tier entity
- As part of the FDR Oversight Program, you will also need to verify that your First Tier entities have contractual obligations in place with their First Tier entities, which are your Downstream entities
- On an annual basis, Covered Entities are required to develop and use an auditing and monitoring plan for their FDRs. Audits should consist of both on-site and desk reviews to determine compliance with operational and compliance requirements. These audits should include a comprehensive review of Medicare requirements and other best practices that are important/specific to your organization
- If there are too many FDRs to audit each year, a risk assessment must be completed to determine which entities to audit. This risk assessment is to identify the FDRs that are most likely to impact the Medicare beneficiaries and/or Covered Entity

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Understand Your FDRs

- Those FDRs with the highest risk should be included in the auditing program for the current year
- When determining how many entities to audit, there is no set number or percentage indicated within Medicare guidance. Each Covered Entity must determine the appropriate amount of auditing needed, related to the organization's size and the amount of risk determined
- Finally, every Covered Entity needs some dedicated resources to oversee its FDR Oversight Program and, preferably, establishing an FDR Oversight Committee
- An FDR Oversight Committee would include the compliance department, business owners associated with the FDRs and representatives from other relevant internal departments
- The FDR Oversight Committee is often a subcommittee of the Medicare Compliance Committee and is responsible for approving the FDR Risk Assessment and the annual auditing and monitoring plan, as well as reviewing monitoring reports, etc. In some organizations, FDR Oversight committees meet as frequently as weekly, and in other organizations they meet on a quarterly basis

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PBM Audit Best Practices

- Determine what PBM audits to conduct. Start with audits that are most likely to yield the greatest return, and to stagger different PBM audits out over a period of time
- Check your PBM contract. If such language is not already in the contract, make sure you revise it to include a clause giving you the right to hire an outside, independent auditor to periodically conduct PBM audits
- It is a good idea to start with a PBM Contractual or Guarantee Rebate Audit. These can often be done without the auditor having to come on site, provided the right data is available. Given the current rebate environment, this type of audit is likely to yield a high financial return
- It's also beneficial to do a separate, but more involved, drug manufacturer rebate audit, which delves into rebate agreement between the PBM and drug manufacturers. These can also yield high financial returns. Given the high dollar amounts involved, it's a good idea to do a rebate audit at least once a year
- Make sure your PBM rebate audits cover a full calendar year period. Given PBM reporting lag times, you will want to wait to do the audit to at least 180 days after the end of the last quarter you wish to have audited

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PBM Audit Best Practices

- Another important PBM audit to consider is a pharmacy audit. This involves a thorough review and analysis of the discounts applied from the average wholesale price (AWP), and pharmacy dispensing fees, to make sure all drug pricing and discount guarantees as stated in the PBM contract have been achieved for the health plan
- When prioritizing other types of PBM audits, it is helpful to look at where the health plan is in the current PBM contract cycle. In general, PBM audits that are not rebate-related or price-related can be staggered out and performed every other year
- If the PBM is new, prioritize doing a benefit audit first. This audit helps health plans determine if the PBM vendor is properly administering the pharmacy benefits
- If the plan has little or no oversight of the PBM fraud waste and abuse programs, then consider prioritizing a pharmacy fraud waste and abuse audit. It's an effective way to preserve the integrity of the pharmacy benefit, avoid monetary losses, and protect members from potentially serious and costly harm, especially given recent surges in opioid abuse

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PBM Audit Best Practices

- For Medicare plans, highly-targeted PBM audits can be a crucial component of an overall risk assessment strategy, as every year, CMS requires Medicare plans to develop a risk assessment plan
- CMS mandates that all First-Tier Downstream and Related Entities (FDRs) be listed and a risk category assigned to each. Individual subject matter experts within the organization should provide key input to the risk plan so it can be determined which vendors pose the highest risks
- Those with high or medium risk should be audited relative to the functions they perform and relative to the Medicare Managed Care Manual sections they're performing against
- Making sure your PBM contract allows you to conduct audits – and conducting these regularly—will help avoid leaving money on the table, protect members, reduce compliance risks and put the plan in a stronger position to demand higher levels of service performance from the PBM

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PBM Monitoring Best Practices

- **What Should You Look For?**
 - *Some important areas to monitor include:*
 - Whether or not your PBM is adhering to contract guarantees
 - *Does the PBM offer network options that include high quality, credentialed pharmacies.*
 - *Does the PBM provide clients with programs to protect against drug manufacturer price inflation.*
 - *Does the PBM provide 24-7 access to pharmacists or other clinicians.*
 - If Prior Authorizations and Step Therapy programs are working properly
 - If your claims are in line with industry benchmarks
 - If your Specialty claims are paying correctly and based on an up-to-date price list
 - *Monitoring should occur ideally on a monthly basis, but at the very least quarterly*

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Off-Boarding

- While effective on-boarding is important – don't forget a check list when off-boarding
- Risks to Monitor
 - *Exposure to PHI, etc.*
 - *Need to get information for regulatory audits after relationship ends*
 - *Reputational Risk*
 - *Unnecessarily providing monetary compensation to vendor once contract ends*

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Questions

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Resources

- Regulatory Requirements: 42 C.F.R. § 422.503 and 42 C.F.R. § 423.504
- Compliance Guidance: <http://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ComplianceProgramPolicyandGuidance.html>
- Training Materials: <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/ProviderCompliance.html>
- PBM Guidance & Best Practices: <http://www.burchfieldgroup.com/health-plan-insurer-blog/pbm-audit-best-practices-tips-for-prioritizing-and-conducting-pbm-audits>

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