

Managing Risk Beyond a Plan's Direct Control: Improving Oversight of a Health Plan's First Tier, Downstream, and Related (FDR) Entities

Our Perspective

Oversight of First Tier, Downstream, and Related (FDR) entities in Medicare Advantage (MA) and Part D plans is an important part of the plan's compliance program. The Centers for Medicare and Medicaid Services (CMS) has been increasing the level of focus on FDRs for MA and Part D plans through their program audits. Plans must implement the FDR oversight requirements in order to meet CMS regulations. It is also good business practice to understand how well the plan's FDRs are performing against regulatory and contractual obligations. Health Plans issuers will want to prepare their compliance programs for FDR oversight to reduce the potential findings from initial CMS oversight audits.

Current Environment

MA and Part D plans are under increasing pressure from CMS to determine that they have a documented and structured process to oversee the activities of their FDRs. Some of the plans that have been audited by CMS under the Medicare program requirements have experienced compliance findings or been placed on corrective action due to a lack of oversight of their FDRs.

As health plans continue to expand the services they delegate to their vendors, they are adding new service providers and vendors to their list of FDRs. In addition to pharmacy benefit managers (PBMs) and network providers, these vendors may include utilization management companies, claims processors, enrollment and billing service providers, risk adjustment medical chart review organizations, and other service providers that may touch the plan's beneficiaries or receive Federal dollars.

Plans must be able to demonstrate that their FDR oversight program meets the CMS regulatory requirements and includes the ability to define and identify FDRs, provide adequate training and education, and perform monitoring and auditing for operational and regulatory compliance. Plus, it is good business practice to evaluate the performance of vendor's, whether it is for contractual performance metrics or for compliance considerations.



CMS Medicare Program Audits and Best Practice Memos

Plans are required to have FDR management and oversight protocols. To determine how well plans are performing their FDR oversight requirements, CMS has included FDR requirements in the CMS program audits for MA and Part D plans. FDR requirements are a significant part of the Compliance Program Effectiveness (CPE) audit protocols and have been included in the program audits since 2010. Some of the FDR requirements CMS tests for include auditing and monitoring programs, compliance and Fraud, Waste, and Abuse (FWA) training programs, testing for exclusion from federal programs, and access to a compliance reporting hotline. The CPE audits conducted by CMS have led to various types of findings regarding FDR oversight across plans. As a result of those audits, CMS has issued a series of memos describing its common findings and best practices that include information on FDR oversight.

Since 2012, CMS has identified lack of oversight by plans as a finding in its Common Findings and Best Practices memos.¹ One consistent finding has been the lack of a coordinated FDR oversight program by the plan. Without a coordinated program, plans may not be able to quickly and efficiently identify FDRs and provide documentation supporting their oversight activities. In addition to the identification of FDR issues via program audits, the 2015 Policy and Technical Changes Final Rule gives CMS the authority to access data directly from FDRs.² CMS is expected to begin requesting data from FDRs soon. This will increase CMS's insight into how well plans are overseeing the activities of their FDRs.

Because of the demanding requirements for FDR oversight, plans have struggled with the ability to manage expectations with their downstream entities. Specifically, this occurs when plans delegate functions to large and complex organizations, such as PBMs and utilization management (UM) organizations. Plans may have difficulty in obtaining agreement with the vendor to obtain the information necessary for proper oversight, which can cause findings for health plans during CMS audits. To help steer plans in the right direction, CMS has suggested, through its best practice memo's, that plans have one owner for FDR oversight³ who manages and implements the required elements.

CMS Requirements for FDR Oversight

When a Medicare Advantage or Part D plan is considering how to perform oversight and monitoring of its FDRs, the plan should first consider the oversight requirements outlined by the CMS in Chapter 21 of the Medicare Managed Care Manual and Chapter 9 of the Medicare Prescription Drug Benefit Manual.

Plans must understand the compliance responsibility they bear when contracting with FDRs. CMS has made it increasingly clear that plans are ultimately responsible for fulfilling the terms and conditions of their contract and as a result are accountable for the actions (and failures) of their FDRs to comply with these requirements. If an FDR fails to comply with a program requirement, the plan bears the consequences regardless of whether the FDR was at fault for the instance of non-compliance.

Plans must also understand the scope of CMS regulations that apply to FDRs. Medicare program requirements apply in their entirety to FDRs delegated by the sponsor to perform administrative or health care services for the sponsor. This includes requirements detailed in CMS regulations or guidance,

regardless of whether Medicare specifically identifies the requirement applies to FDRs. The exception to these rules is made for FDRs that perform services unrelated to the core administration of the contract, such as legal or accounting services. These contractors do not meet the definition of an FDR.

Because FDRs are responsible for complying with all Medicare regulations, FDRs should maintain policies and procedures that cover all the requirements outlined in Medicare regulations. Additionally, FDRs must either adopt or acknowledge the plan sponsor's code of conduct or have their own code of conduct with the same elements, including a fraud, waste, and abuse (FWA) plan, as that of the plan sponsor. FDRs are also subject to the regulations related to screening their employees against the OIG and GSA exclusions lists, which should be monitored monthly. Prior to contracting, the plan should perform a pre-delegation review of the contractor, determine if the entity is capable of meeting the Medicare requirements, which would include validating that the contractor itself and that its employees are not excluded from participating in federal programs per the exclusion lists.

Lastly, plans must understand which core compliance functions can be delegated and which cannot be delegated. CMS does not allow plans to delegate the core functions of the compliance department, such as the role of Compliance Officer, the function of the Compliance Committee, and reporting up to the sponsor's senior management. However, the sponsor can delegate specific compliance activities such as monitoring, auditing, and training.

Identification of FDRs

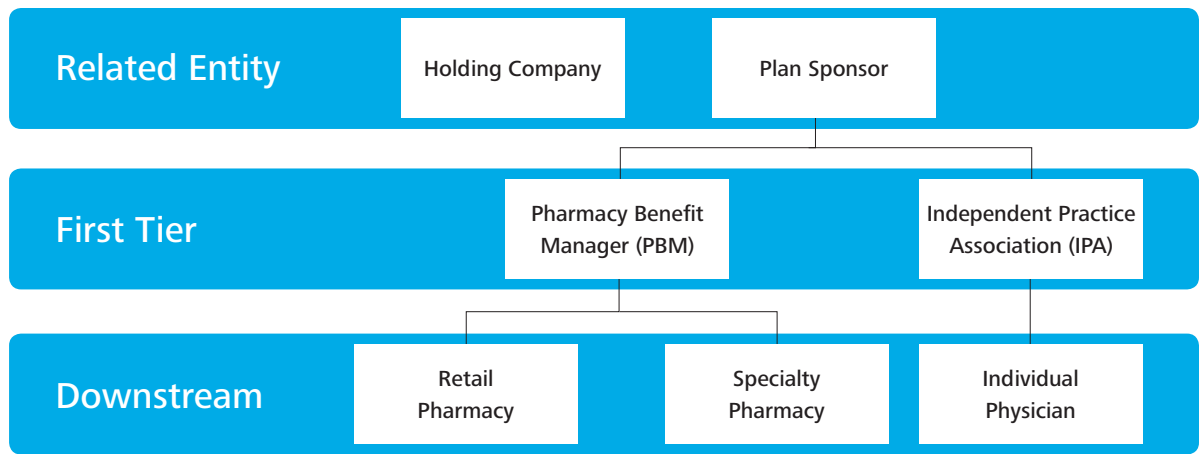
Plans must have a documented procedure in place to properly identify which downstream vendors are considered FDRs and therefore must comply with CMS requirements. Plans often have a difficult time distinguishing between an FDR and a vendor or contractor. The chart represents the relationship between the plan and its vendors that can help understand the FDR relationship to the plan.

The FDR is a vendor that would meet the definition

¹ HPMS Best Practice memos dated; January 20, 2012, July 30, 2013, and August 27, 2014

² 42 CFR Parts 417, 422, 423, et al. Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Final Rule. See Section 23. Establish Authority To Directly Request Information From First Tier, Downstream, and Related Entities (§§ 422.504(i)(2)(i), and 423.505(i)(2)(i))

³ HPMS Best Practice memos dated; July 30, 2013, page 13



described by CMS in Chapter 21 of the Medicare Managed Care Manual and Chapter 9 of the Medicare Prescription Drug Benefit Manual. The chapters provide a number of examples of types of MA and Part D services provided to enrollees as well as the factors to consider in determining whether a vendor is an FDR. Some of the more common services MA and Part D plans delegate include⁴ (for a complete listing, see the Medicare Chapters):

- Sales and marketing;
- Utilization management;
- Quality improvement;
- Pharmacy Benefit Management
- Administration and tracking of enrollees’ drug benefits, including TRiOP balance processing;
- Enrollment, disenrollment, membership functions;
- Claims administration, processing and coverage adjudication;
- Bid preparation; and
- Health care services

Combining the list of services that may be delegated with the factors CMS recommends plans consider when delegating can help plans develop a solid approach to identifying which contracted entities are FDRs. The factors to consider in delegating include⁵:

- Whether the function is something the sponsor is required to do or to provide under its contract with CMS, the applicable federal regulations or CMS guidance;
- The extent the function directly impacts enrollees;
- The extent the delegated entity has interaction with enrollees, either orally or in writing;
- Whether the delegated entity has access to beneficiary information or personal health information;
- Whether the delegated entity has decision-making authority (e.g., enrollment vendor deciding time frames) or whether the entity strictly takes direction from the sponsor;
- The extent to which the function places the delegated

- entity in a position to commit health care FWA; and
- The risk that the entity could harm enrollees or otherwise violate Medicare program requirements or commit FWA.

It is important that plans have a process to identify FDRs so the plan can provide a list of FDRs to CMS when requested, as required in a CMS program audit. The plan should also use its list of FDRs to develop its FDR risk assessment and its FDR auditing and monitoring program.

Monitoring and Auditing

In the Medicare Managed Care Manual and the Prescription Drug Benefit Manual, CMS requires that all plans have a documented plan to monitor and audit FDRs to ensure compliance with applicable Medicare requirements. This work plan must outline the sponsor’s strategy and must identify the number of entities that will be audited and how entities will be selected for an audit. If the sponsor contracts a large number of FDRs and will not be able to audit them all annually, then a risk assessment should be conducted to identify the highest risk entities and those entities should be targeted for an audit.

When auditing and monitoring FDRs, plans should ensure that the FDR is also monitoring and auditing their downstream vendors as well. For example, if a plan contracts with an IPA or hospital group as a first tier entity, the plan should ensure that the first tier entity is also auditing its downstream contractors, which in this case are individual providers and/ or hospitals.

In the case that one or several of a plan’s FDRs perform

⁴ Prescription Drug Benefit Manual Chapter 9 - Compliance Program Guidelines and Medicare Managed Care Manual Chapter 21 – Compliance Program Guidelines, page 9

⁵ Prescription Drug Benefit Manual Chapter 9 - Compliance Program Guidelines and Medicare Managed Care Manual Chapter 21 – Compliance Program Guidelines, page 12

their own audits, the plan should obtain a copy of the FDR's audit work plan and any audit results. Additionally, the plan should review reports and metrics that allow the plan to adequately monitor the FDR's compliance in high risk areas such as payment accuracy and timeliness as well as potential FWA.

Plans should also ensure that FDRs performing their own audits are implementing Corrective Action Plans (CAPs) when instances of non-compliance are identified. Accordingly, plans should validate that the appropriate remediation and follow-up activity occurs after an FDR implements a corrective action and all deficiencies are properly documented to resolution.

Training and Education

Training and education plans from each FDR should also be reviewed to ensure that FDRs perform all required training at regular intervals, particularly including FWA, which is required within 90 days of hire and annually thereafter. Additionally, plans should ensure that all training conducted by FDRs is documented and records maintained for at least 10 years.

Lastly, plans must ensure that their FDRs receive all appropriate compliance related communications and guidance as it is released by CMS. This includes new and existing CMS guidance, HPMS memos, and other relevant regulatory guidance.

Conclusion

The FDR oversight program is an important requirement for an effective compliance program. Health plans are required to identify their FDRs and understand if those FDRs are meeting the requirements of the Federal programs in which the plan is participating. However, it is not just to meet the plan's regulatory requirements that an FDR program is important. Leading business practice would indicate that plans will want to know if their FDRs are meeting the agreed upon service levels, delivering the services delegated, and monitoring for fraud at the delegate level.

Plans that participate in Federal programs should ensure that they have a well-developed FDR program. CMS guidance found in the Medicare Compliance Manuals provides guidance on the required elements of FDR oversight. The first step a plan should consider taking is to identify a single point of oversight for its FDRs. Identification of its FDRs is the next step and is very important for appropriate oversight. Once the plan has identified its FDRs, the oversight becomes an issue primarily of auditing, monitoring, training, and education. Once each of these steps is implemented, the plan will want to monitor and manage the performance of the FDR oversight program to improve its performance.

FDR Oversight and Health Insurance Exchanges (HIX)

The information in this article is primarily focused on MA and Part D plans compliance requirements for FDRs. However, the FDR requirements for health plans participating in MA and Part D plans and those participating in the HIX market are similar. The major difference, at this point in time, is that the sub-regulatory requirements for MA and Part D plan oversight activities are more fully developed than that of the HIX sub-regulatory requirements. Regulations defining requirements for Health Insurance Exchanges establish that a health plan issuer (issuer) maintains responsibility for not only the issuer's compliance with HIX requirements, but also compliance of any of its delegated or downstream entities.⁶ HIX issuers can expect that sub-regulatory guidance similar to those in the MA and Part D plans will be developed for oversight of the HIX issuers. Health plans that have moved into the HIX market will likely experience similar pressure as that market continues to develop and HIX compliance requirements are more clearly defined.

Although CMS has not yet begun to perform oversight audits in the HIX market, the risks associated with FDR oversight are still relevant to issuers. An FDR that does not perform its services according to the regulatory requirements puts the issuer at risk for regulatory (such as future fines, Civil Money Penalties, etc.) and reputational (marketplace) issues. Also, CMS has indicated that in the next year it will begin to perform compliance reviews of issuers.⁷ CMS is likely to use the CMS MA and Part D CPE audit protocols which include the FDR oversight requirements, for HIX issuers. With a look-back period of one year, issuers will want to make sure that their Compliance Programs include the testing and oversight of their FDRs today.

The approach found in the MA and Part D compliance chapters and CMS best practice memos is an informational resource for those HIX issuers building an FDR oversight model. Because the CMS regulations for HIX issuers specifically indicate that any FDR is subject to all requirements the issuer is, plans will want to prepare their compliance program to meet the standards of the CMS Medicare program.

⁶ § 45 CFR 156.340 Standards for downstream and delegated entities.

⁷ FINAL 2016 Letter to Issuers in the Federally-facilitated Marketplaces dated; February 20, 2015, page 46.

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