FDR compliance newsletter

December 2022 – Issue 35

Third-Party Marketing Organization (TPMO) final rule

The Centers for Medicare & Medicaid Services (CMS) has expanded the definition of TPMOs. It now includes organizations that are compensated to perform lead generation, marketing, sales and enrollment-related functions. CMS expects plan sponsors and their TPMOs to produce materials that are not misleading or confusing. As part of the CMS oversight process, TPMOs are required to submit all materials that meet the CMS definition of marketing directly into the Health Plan Management System (HPMS).

CMS also requires TPMOs to use the following disclaimer on all marketing materials: "We do not offer every plan available in your area. Any information we provide is limited to those plans we do offer in your area. Please contact Medicare.gov or 1-800-MEDICARE to get information on all of your options." This disclaimer cannot be changed.

Medicare Advantage/Part D plans are expected to have oversight of TPMOs. Oversight expectations of TPMOs goes beyond general First Tier, Downstream and Related Entity (FDR) oversight responsibilities. When a TPMO is not considered an FDR, the MA/Part D plan sponsor still must ensure the TPMO adheres to all applicable CMS requirements.

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Quick links

- **Archived newsletters**
- **Aetna® FDR guide (updated July 2022)**
- **Medicare managed care manual**
- **Medicare prescription drug benefit manual**
- **CVS Health® Code of Conduct (updated November 2022)**

Exclusion list links:

- **OIG list of excluded individuals and entities (LEIE)**
- **GSA System for Award Management (SAM)**

Links not working? Go to **SAM.gov/SAM/** to access the site directly.

We have a robust Medicare compliance program. It includes communication with our Medicare FDRs. Patrick Jeswald is our dedicated Medicare Compliance Officer. You can send questions or concerns to him at **MedicareFDR@Aetna.com**.

Downstream entity oversight process

As part of the CMS requirement in Chapter 9 of the Prescription Drug Benefit Manual and Chapter 21 of the Medicare Managed Care Manual, section 50.6.6 Monitoring and Auditing FDRs, CVS Health® audits and monitors your organization based on your status as an FDR. Your organization also must audit and monitor FDRs that your organization contracts with to perform Medicare services for CVS Health. Here are a few questions and answers to help explain how your organization should be evaluating and overseeing your FDRs.

How do we determine if a downstream entity is an FDR?
Medicare program requirements apply to FDRs to which the sponsor has delegated administrative or health care service functions relating to the sponsor's Medicare Parts C and D contracts. Chapter 9 of the Prescription Drug Benefit Manual and Chapter 21 of the Medicare Managed Care Manual, section 40 Sponsor Accountability for and Oversight of FDRs, outlines areas of consideration when determining if an entity qualifies as an FDR. The chapter suggests evaluating the following factors when determining FDR status: the type of services being performed (many examples of functions that would give rise to FDR status are listed); the impact of the services on beneficiaries; the entity's access to protected health information; the entity's decision-making authority; the entity's ability to commit fraud, waste or abuse; and the overall risk associated with the entity. While a specific methodology is not outlined in the chapter, your organization should have a process that considers all of the factors listed above. Be sure to consistently evaluate the FDR status of subcontractors performing services on behalf of CVS Health. Our FDR Guidebook also has information on identifying your FDRs and includes a grid of examples. If you need a copy of our FDR Guidebook, email **MedicareFDR@Aetna.com**.

My organization determined an entity is an FDR. What are our oversight obligations?
If your evaluation process determines an entity is a downstream entity for CVS Health, be sure to let us know about this relationship. Including if any of the FDR services are being performed offshore. You will want to ensure there is an executed contractual agreement between your organization and the entity that contains all CMS-required provisions (42 CFR 423.505(i) and 42 CFR 422.504(i)). Additionally, make sure processes are in place for monitoring that the entity meets compliance and operational requirements. Such as ensuring an oversight policy is in place, obtaining compliance attestations and conducting monitoring and/or auditing activities of the entity's compliance program and performance of operational processes. When CVS Health evaluates or audits your organization's compliance program, we will ask for evidence of oversight of your FDRs as part of the review.

What if oversight of our FDRs show the entity is not compliant with a Medicare requirement?
Just as CVS Health is required to hold your organization accountable for noncompliance and require remediation of deficiencies, your organization must do the same for your FDRs. Section 50.7.2 of Chapter 9 of the Prescription Drug Benefit Manual and Chapter 21 of the Medicare Managed Care Manual outlines key components of Corrective Plans. Like requiring the FDR to determine the root cause of the failure, tailoring a corrective action to specifically address the deficiency and the importance of validating compliance after the corrective action is in place. In addition, if you identify a compliance or FWA that impacts CVS Health or Aetna®, you must report it to us. Review the reporting poster for more information, located in our FDR Guidebook.

Continued on the next page.

What documentation do we need to retain related to oversight of our FDRs?
All Medicare documentation must be retained for at least 10 years. This includes contracts with your FDRs, documentation of oversight activities, evidence of corrective action plans and remediation and documentation to support your FDR evaluation process.

Reporting issues of noncompliance and FWA to CVS Health

Did you know, based on your organization's status of a Medicare FDR, you have an obligation to report issues of non-compliance and FWA to plan sponsors (like Aetna® and CVS Health®)?

The requirement for reporting such issues can be found in the Medicare Managed Care Manual Chapter 21 – Compliance Program Guidelines and Prescription Drug Benefit Manual Chapter 9 – Compliance Program Guidelines, section 50.4.2 Communication and Reporting Mechanisms. It states that the sponsor must require FDRs to report compliance concerns and suspected or actual violations related to the Medicare program to the sponsor. CVS Health has included this requirement of our FDRs in our Medicare contracts and addendums, and our FDR training packet and compliance attestations. We also test compliance as part of Compliance Program Effectiveness (CPE) oversight processes. You can refer to the Medicare Compliance FDR Guidebook for further details.

We've seen an upward trend in failures for this requirement in our CPE oversight activities.

FDRs should be aware of the requirement and ensure that a written policy/procedure is in place which demonstrates the mechanism for reporting to plan sponsors. Here is sample language that could be included in your organizations written policy or procedure: *"Entity Name" will cooperate with appropriate federal, state and local authorities who are investigating possible unlawful conduct. Additionally, "Entity Name" will report compliance issues and potential FWA, as required to the appropriate CMS Medicare Plan Sponsor.*

There are a number of ways to report suspected or detected noncompliance or potential FWA.

- CVS Health Ethics Line: **1-877-287-2040** (**1-877-287-2040**)**(TTY:** 711)
- CVS Health Online Ethics Line **CVSHealth.com/EthicsLine**
- Write us: Chief Compliance Officer, CVS Health One CVS Drive, Woonsocket, RI 02895

If you have additional questions, you can email **MedicareFDR@Aetna.com**.