



First tier, downstream and related entities (FDR) 101

Fallon Health developed this guide to summarize Medicare compliance requirements for FDRs and Medicare Advantage Organizations (MAO or Plan) like ours. For more information about the requirements listed below and other contractual requirements associated to working with Fallon Health, please refer to the *Government Program Addendum*. Additionally, Fallon Health sends out monthly communications focused on our FDRs. To subscribe, please email ComplianceBlast@fallonhealth.org.

General definitions

The Centers for Medicare & Medicaid Services (CMS): The federal agency which administers the Medicare Advantage (MA) Program and Prescription Drug Plan (Part D) Program. The Medicare Advantage program is also known as Medicare Part C (Part C).

Government Program Addendum (GPA): An addendum to Fallon's contract with a government program vendor that is a requirement of contracting, and which outlines the applicable regulatory requirements associated with being a government program vendor.

First tier entity: Any party that enters into a written arrangement 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: Any party that enters into a written arrangement 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).

Related entity: 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. (See 42 C.F.R. § 423.501).

What is an FDR?

Plans may delegate administrative or health care service functions to a third party, like a pharmacy benefit manager or field marketing organization. This relationship may cause the subcontracted entity to be identified by the Plan as an FDR if the delegated function is required of the Plan under its contract with CMS.

Below are some examples of core functions that relate to Fallon Health's Parts C and D contracts:

- Sales and marketing
- Utilization management
- Quality improvement
- Applications processing
- Enrollment, disenrollment, membership functions

- Claims administration, processing and coverage adjudication
- Appeals and grievances
- Licensing and credentialing
- Pharmacy benefit management
- Hotline operations
- Customer service
- Bid preparation
- Outbound enrollment verification
- Provider network management
- Processing of pharmacy claims at the point of sale
- Negotiation with prescription drug manufacturers and others for rebates, discounts or other price concessions on prescription drugs
- Administration and tracking of enrollees' drug benefits, including TrOOP balance processing
- Coordination with other benefit programs such as Medicaid, state pharmaceutical assistance or other insurance programs
- Entities that generate claims data
- Health care services

Because FDRs have been delegated to perform a core function of a Plan's Medicare program, they must follow Medicare program requirements and regulations, which the Plan is ultimately responsible for overseeing. Accordingly, Plans must develop and implement processes to appropriately determine which vendors are FDRs.

How does Fallon determine which vendors are FDRs?

In addition to the functions above, Fallon Health also considers the following factors in determining whether a vendor is an FDR:

- 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, or under its contract with the State
- To what extent the function directly impacts enrollees
- To what extent the delegated entity has interaction with enrollees, either orally or in writing
- Whether the delegated entity has access to beneficiary information or protected health information (PHI)
- 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 fraud, waste or abuse
- The risk that the entity could harm enrollees or otherwise violate Medicare or Medicaid program requirements or commit fraud, waste, and abuse (FWA)

Fallon Health utilizes the above factors as well as applicable federal and state regulations and guidance to appropriately identify FDRs.

What are the requirements as an FDR?

As an FDR, there are certain regulatory requirements that must be met in order for the Plan to remain compliant with Federal and/or State contracts. The source of these requirements is the Code of Federal Regulations (CFR). They are further described within the Medicare Managed Care Manual, Chapter 21 – Compliance Program Guidelines and Prescription Drug Benefit Manual, Chapter 9 – Compliance Program Guidelines.

General requirements

Right to monitor, audit, and request documentation

FDRs must allow Plans access to information pertinent to the Plan's contract with the FDR. This information includes, but is not limited to, any books, contracts, computer or other electronic systems (including medical records, report code, claims processing).

Compliance with all applicable contract requirements, regulations and guidance

FDRs must comply not only with the terms of their contract with the Plan, but also all applicable Medicare requirements and federal and state regulations and guidance unless otherwise noted by the Plan in a separate, program-specific addendum.

Exclusion screening

Individuals or entities that have been excluded from participating with Medicare, Medicaid and other Federal or State health care programs cannot directly or indirectly support the administration or delivery of Medicare program services. FDRs must screen all full-time, temporary and contracted employees, volunteers, vendors, and board members upon or before hire/contracting and monthly thereafter against the [Office of the Inspector General List of Excluded Individuals and Entities \(OIG LEIE\)](#) and [the System for Awards Management \(SAM\)](#).

Evidence of monthly screenings must be recorded and retained as applicable and provided to Fallon Health if requested. Evidence can be in the form of a screen shot, if manual searches are completed, or if your organization performs a more automated system, the documentation may be based on the information within that system. The documentation should clearly identify the name of the entity/individual checked, the date the check was performed, and the results of the check.

Positive matches to the exclusion databases must be reported immediately to Fallon Health.

If your organization delegates any functions to a downstream or related entity, you must ensure that the downstream entity is also completing the exclusion checks for the same individuals as noted above. Fallon Health may request documentation of these checks to ensure that your organization and its downstream entities are in compliance.

Standards of Conduct/Code of Conduct and compliance policies

FDRs are required to maintain and distribute Standards of Conduct/Codes of Conduct (SOC/COC) and compliance policies to all employees, volunteers, contractors, board members, and downstream and related entities within 90 days of hire/contracting and annually thereafter. These documents must be reviewed annually or sooner as needed.

To help FDRs meet this requirement, Fallon Health distributes [Fallon Health's Vendor and Supplier Code of Conduct](#) (VSCC) to FDRs upon contracting and annually thereafter. Fallon Health's VSCC may be distributed and required as a condition of employment in lieu of an internal SOC/COC.

Fraud, Waste, and Abuse (FWA) and Medicare compliance training

FDRs are required to provide employees, contractors, board members, and downstream and related entities with Medicare FWA and general Medicare compliance training within 90 days of hire/contracting and annually thereafter. FDRs are required to maintain evidence of both FWA and general Medicare compliance training, which may include training logs, attestations and training programs.

Evidence that this requirement is being met can be requested by Fallon Health at any time.

Your organization may be exempt from the FWA training requirement if it is considered “deemed” by CMS. You are deemed if you are (1) enrolled into Medicare Parts A or B, or (2) accredited as a supplier of Durable Medical Equipment Prosthetics Orthotics and Supplies (DMEPOS).

Organizations must use CMS’s training content¹ found here:

- [Medicare Parts C and D General Compliance Training](#)
- [Combating Medicare Parts C and D Fraud, Waste and Abuse Training](#)

Reporting mechanisms

FDRs must have a system or process in place to report issues of non-compliance and suspected/potential FWA concerns. The system must maintain confidentiality and anonymity, if desired. Such reporting must also be subject to non-retaliation and non-intimidation when done in good faith.

Additionally, your organization must have a process to report issues of non-compliance and FWA relating to Fallon Health directly to Fallon Health.

Record retention

CMS and other federal regulators require that all information associated with Medicare Advantage programs must be maintained for at least ten years. This includes, but is not limited to, training documentation, exclusion screenings, data, and report code.

Downstream and related entity oversight

If your organization is a first tier entity that contracts with a downstream or related entity to perform services under your contract with Fallon Health, you must monitor and audit that downstream or related entity to ensure contract and program requirements are being met. In addition, it is expected first tier entities will impose corrective actions when deficiencies are identified, which may, in some cases, mean termination of a contract with the downstream or related entity. Fallon Health has the right to request evidence of this monitoring and auditing.

Offshore operations

CMS requires that all organizations using offshore subcontractors submit specific subcontract information and attest to having taken appropriate steps to address the specific risks associated with the use of subcontractors outside the United States and its territories.

Your organization must therefore submit one attestation for each offshore subcontractor you have engaged to perform Medicare-related work required under your contract with Fallon Health, including your own organization if it has facilities or employees located outside of the US and its territories. This attestation includes, in part:

1. Offshore subcontractor’s name and functions
2. Description of the PHI provided to the offshore subcontractor
3. Offshore subcontracting arrangement safeguards adopted to protect beneficiary information
4. Offshore subcontractor audit requirements

The Offshore Attestation form is available on [Fallon Health’s Government Program Vendor website](#) and must be submitted to Fallon within 30 calendar days of signing the offshore subcontract.

Please note that the information included in this guide only outlines some of the responsibilities an FDR has under their contract with Fallon. The Government Program Addendum further outlines the applicable regulatory and contractual requirements associated with being an FDR.

Questions? Email ComplianceBlast@fallonhealth.org or call Kasey Ciolfi at 1-508-368-9514.

18-672-001 Rev. 00 2/18

¹ Organizations may download the CMS content into existing compliance and FWA training materials/modules.