



Compliance Program Guide for First Tier, Downstream and Related Entities (FDR)

Overview and Purpose

Medicare Advantage (MA) and Programs of All-inclusive Care for the Elderly (PACE) plans (“Medicare programs”) may contract with external entities or individuals to provide administrative and health care services like a pharmacy benefit manager, physician-hospital organization and sales agents. This delegation may cause the entity or individual to be identified as an FDR if the services delegated are required under Fallon Health’s contract with the Centers for Medicare & Medicaid Services (CMS).

Fallon Health maintains ultimate responsibility for the services we deliver to our members, including services provided by our FDRs. To that end, we hold our FDRs to the same requirements that we are by CMS.

This document is intended to assist your organization, employees, providers, and downstream entities in fully understanding not only applicable Medicare program requirements, but the expectation that all Fallon Health business will be conducted ethically, with integrity, and in compliance with applicable laws, regulations and requirements.

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Definitions

Abuse – Includes actions that may, directly or indirectly, result in: unnecessary costs to the Medicare Program, improper payment, payment for services that fail to meet professionally recognized standards of care, or services that are medically unnecessary. Abuse involves payment for items or services when there is no legal entitlement to that payment and the provider has not knowingly and/or intentionally misrepresented facts to obtain payment. Abuse cannot be differentiated categorically from fraud, because the distinction between “fraud” and “abuse” depends on specific facts and circumstances, intent and prior knowledge, and available evidence, among other factors.

Audit – Refers to a formal review of compliance with a particular set of internal (e.g., policies and procedures) and/or external (e.g., laws and regulations) standards used as base measures. (See 42 CFR §§422.2 and 423.501).

Business partners and health care providers – Any non-employee contracted, directly or indirectly, to perform a business function or provide goods or a service for or on Fallon Health’s behalf. Examples are delegated and non-delegated health care providers, delegated entities, pharmacies, sales agents, sales agencies, vendors, and suppliers of administrative goods and/or services, contractors and delegates. Providers, vendors and suppliers are considered Business Partners and may also be identified as an FDR.

Conflict of interest – An improper personal or professional gain on an employee’s part or that of a member of an employee’s immediate family (spouse, parent, child or sibling) that could affect the employee’s judgment or decisions the employee makes on behalf of Fallon Health or related to any contract Fallon Health has including with any state or federal agency. It is a situation or relationship that could interfere with an employee’s ability to make fair, arm’s length decisions on behalf of Fallon Health.

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 Fallon Health 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 CFR §§422.2 and 423.501).

Employee – Persons employed by Fallon Health or an FDR who provide health or administrative services for a Medicare beneficiary enrolled in a Fallon Health Medicare program. (See 42 CFR §§422.2 and 423.501).

FDR – A first tier, downstream or related entity of Fallon Health.

First tier entity – Any party that enters into an acceptable written arrangement with Fallon Health to provide administrative or health care services to a Medicare-eligible individual under a Fallon Health-administered Medicare program. (See 42 CFR §§422.2 and 423.501).

Fraud – Knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any health care benefit program or to obtain (by means of false or fraudulent pretenses, representations, or promises) any of the money or property owned by, or under the custody or control of, any health care benefit program (18 U.S.C. §1347).

Monitoring – Reviews that are repeated regularly during the normal course of operations. These activities may occur to confirm ongoing compliance even in the absence of identified problems or corrective actions are undertaken and effective. (See 42 CFR §§422.2 and 423.501).

Related entity – Any entity that is related to Fallon Health by common ownership or control and meets one of the following criteria: performs some of Fallon Health’s management functions under contract or

delegation; furnishes services to enrollees under an oral or written agreement; or leases real property or sells materials to Fallon Health at a cost of more than \$2,500 during a contract period. (See 42 CFR §§422.2 and 423.501).

The Centers for Medicare & Medicaid Services (CMS) – An agency within the U.S. Department of Health and Human Services that is responsible for the administration of the federal Medicare and Medicaid programs.

TrOOP (True Out of Pocket) Costs – Costs that an enrollee must incur on Part D covered drugs to reach catastrophic coverage. (See CFR §423.100).

Volunteer – Any individual who offers one's time, skill, knowledge, and services with no expectation of reward or personal gain.

Waste – The overutilization of services, or other practices that, directly or indirectly, result in unnecessary costs to the Medicare program.

Key takeaways

Applicability

The compliance program elements and requirements contained within this document apply to your organization's employees, contracted personnel, providers/practitioners, governing body members, and downstream entities providing health care or administrative services for Fallon Health's Medicare programs.

Non-compliance

Your organization must comply with the compliance program requirements set forth in this document. If your organization does not meet these requirements, depending on the severity of the non-compliance, Fallon Health may require re-training and education, development of a corrective action plan (CAP), or contract termination.

For a more detailed explanation of our response to non-compliance, please review our [Business Partners and Health Care Providers Disciplinary Standards Policy](#).

Annual attestation

On an annual basis, Fallon Health requires an authorized representative from your organization to attest to its compliance with the compliance program requirements in this guide. Fallon Health may not require supporting evidence of compliance each year, but your organization must maintain documentation for each requirement for no less than ten years.

FDR Basics

What is a First tier, downstream and related entity (FDR)?

Fallon Health 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 Fallon Health as an FDR if the delegated function is required of Fallon Health 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 Fallon Health's Medicare program, they must follow Medicare program requirements and regulations, just as Fallon Health is required to do when providing a core function directly, which Fallon Health is ultimately responsible for overseeing. Accordingly, Fallon Health must develop and implement processes to appropriately determine which vendors are FDRs.

How does Fallon Health 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 determine FDRs.

Compliance program requirements

Fallon Health is required to implement an effective compliance program as a Medicare program sponsor. The source of these requirements is the Code of Federal Regulations (CFR). They are further described in *Section 30 – Overview of Mandatory Compliance Program* of the Medicare Managed Care Manual, Chapter 21 – Compliance Program Guidelines and Prescription Drug Benefit Manual, Chapter 9 – Compliance Program Guidelines. These requirements apply to our FDRs (42 CFR § 422.504(i)).

Below provides basic information on the general requirements for an effective compliance program.

Policies, procedures and standards of conduct

Fallon Health's overall expectation for compliance begins with commitment to comply with all federal and state regulations, standards and sub-regulatory guidance. Fallon Health maintains written policies, procedures and a Code of Conduct so all employees, governing body members, and FDRs know and understand their individual responsibility for compliant and ethical business practices.

FDRs must have written policies, procedures and standards of conduct in place that speak to their organization's commitment to compliance and reinforce the principle that compliance is the responsibility of everyone. Fallon Health may request and subsequently review policies, procedures, and standards of conduct of our FDRs to confirm compliance with Medicare program requirements.

Fallon Health also maintains and distributes a [Business Partners and Health Care Providers Code of Conduct](#) (Code) that is provided at the time of contracting and at least annually. Additionally, the Code is available on the [Compliance for Business Partners and Health Care Providers page](#) of the Fallon Health website at fallonhealth.org.

Conflicts of interest

Fallon Health employees, board members and FDRs and their employees must avoid conflicts of interest or even the appearance of a conflict of interest in its business dealings with or on behalf of Fallon Health.

Your organization must have a conflicts of interest policy that provides guidance to employees, providers, governing body members and downstream entities about avoiding conflicts of interest. Additionally, your organization must have procedures in place to monitor potential conflicts of interest of individuals in supervisory or leadership positions.

Training and education

Fallon Health provides training and education to all employees and board members upon hire and annually thereafter. The training program is designed to reinforce our company's commitment to compliance, monitor the effectiveness of our compliance program, and to maintain a training documentation record.

FDRs must ensure governing body members and all employees, providers, and downstream entities providing health care or administrative services for Fallon Health's Medicare programs complete relevant compliance and FWA training upon hire/contract and annually thereafter. FDRs must maintain evidence of training completion for ten years.

Fallon Health reserves the right to request proof from FDRs that the requirement has been met, regardless of the method used for training. What must be retained and would be submitted, if requested, would include tracking logs, policies and procedures, and other documentation that specifies the time, attendance, topic(s) covered, certifications of completion and scores of any training and tests administered (if applicable).

Note, FDRs that obtain FWA certification through enrollment into the Medicare Program or accreditation as Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) are deemed to have met their FWA training.

Record retention and management

CMS and other federal regulators require that all information associated with Medicare programs must be maintained for at least ten years (see CFR §§522.504 and 523.505). FDRs must therefore retain books, records, documents, and other evidence that supports the functions that are being performed on Fallon Health's behalf for a minimum of ten years.

Along with CMS, Fallon Health maintains the right to monitor, audit, and request documentation. Therefore, your organization must allow Fallon Health the right to access or request information pertinent under our contract. This information includes, but is not limited to, any books, contracts, computer or other electronic systems (including data, medical records, report code, claims processing), training documentation, and exclusion screenings.

Effective lines of communication and reporting

Fallon Health works diligently to foster a culture of compliance throughout the organization by regularly communicating the importance of performing jobs in compliance with regulatory requirements and reinforcing the company expectations of ethical and lawful behavior. Fallon Health also supports and enforces a non-retaliation policy for incidents reported in good faith. Employees involved in incidents of retaliation are subject to disciplinary action up to and including termination of employment.

As an FDR, your organization must have effective lines of communication that foster compliance and the ability for employees to report suspected or detected non-compliance and FWA concerns while also administering a non-retaliation policy for incidents reported in good faith.

Requirement to report

FDRs, their employees, and downstream entities who suspect potential or actual FWA or other instances of non-compliance have a duty to report these instances to Fallon Health.

Methods for Reporting Suspected or Detected Noncompliance to Fallon Health

Fallon Health has implemented systems to receive, record, and respond to compliance questions or reports of potential or actual non-compliance from employees, members, providers and FDRs. Reports may be made by emailing Compliance@fallonhealth.org or by anonymously calling **Fallon Health's Compliance Hotline at 1-888-203-5295**.

Additionally, reports of suspected FWA or false claims related to Fallon Health business can be submitted to InternalAudit-FWAInquiries@fallonhealth.org.

Monitoring and auditing

Monitoring and auditing activities are crucial for the identification of compliance risks and are an integral part of Fallon Health's compliance program. Our system allows us to evaluate compliance with Medicare regulations, sub-regulatory guidance, contractual agreements, policies and procedures, and all applicable State and Federal laws. In addition to internal operations, our oversight program includes the operational performance and compliance programs of Fallon Health's FDRs. Issues identified are reviewed to determine if corrective actions are needed in order to be in compliance with applicable regulatory requirements. This process of self-identification and corrective action, along with monitoring that such actions are effective, is a key element of our program.

FDRs must also implement monitoring and auditing systems to test their operations and functions performed on behalf of Fallon Health. Effective systems should be ongoing with the aim of identifying issues early, correcting deficiencies, and implementing procedures to prevent future deficiencies or issues. Fallon Health maintains the right to audit and monitor our FDR's operational compliance on an ongoing basis to test and confirm the operational and contractual performance of all functions performed by our FDRs.

Exclusion monitoring

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 governing body members upon or before hire/contracting and monthly thereafter against the Office of the Inspector General's [List of Excluded Individuals and Entities](#) (OIG LEIE), the [System for Award Management](#) (SAM) and applicable State Medicaid exclusion lists, such as MassHealth's [List of Suspended and Excluded Providers](#) and New York's Office of the Medicaid Inspector General [Medicaid Exclusions](#).

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 process, 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 to Fallon Health within five business days.

Oversight of downstream or related entities

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, including the above referenced exclusion sources for the same individuals as noted, and audit that downstream or related entity to ensure contract and program requirements are being met. This includes ensuring that business associate agreements are in place as required and updated as needed. 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 to ensure that your organization and its downstream entities are in compliance.

Offshore resources

CMS requires that all organizations using offshore locations or 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 United States and its territories. The required information within the attestation includes, in part:

- offshore subcontractor's name and functions,
- description of the PHI provided to the offshore subcontractor,
- offshore subcontracting arrangement safeguards adopted to protect beneficiary information, and
- offshore subcontractor audit requirements.

The [Offshore Subcontractor Attestation](#) is available on Fallon Health's Compliance for Business Partners and Health Care Providers page and must be submitted to Fallon Health within 30 calendar days of signing the offshore subcontract. Return the completed form by sending an email to BPHPOversight@FallonHealth.org.

FDR Resources

Toolbox

Policies, procedures and standards of conduct	
Code of Conduct	Use and distribute your organization's or our Business Partners and Health Care Providers Code of Conduct
Training and education	
General compliance training	CMS general compliance training module
FWA training	CMS FWA training module
Governing body	Request sample compliance and FWA training for governing bodies by emailing BPHPoversight@fallonhealth.org
Reporting	
Reporting to Fallon Health	Anonymous and confidential hotline: 1-888-203-5295 Corporate Compliance: Compliance@fallonhealth.org FWA & Special Investigation Unit: InternalAudit-FWAInquiries@fallonhealth.org
Exclusion monitoring	
OIG LEIE	https://oig.hhs.gov/exclusions/index.asp
SAM	https://www.sam.gov/SAM/
MassHealth	https://www.mass.gov/service-details/learn-about-suspended-or-excluded-masshealth-providers
New York	https://omig.ny.gov/medicaid-fraud/medicaid-exclusions
Monthly attestation	Complete this First tier entity exclusion screening attestation each month to report on your organization's ongoing exclusion screening by the 15th of each month.
Oversight of downstream or related entities	
Monitoring downstream compliance	Use an attestation like this sample annual attestation to evaluate the compliance of your downstream or related entities.
Offshore resources	
Notification to Fallon Health	Use this Offshore Subcontractor Attestation to submit notification of use of an offshore location or subcontractor to perform services that involve the processing, transferring, handling, storing or accessing of Medicare member PHI. Submit completed form to BPHPoversight@fallonhealth.org
Effective lines of communication contact information	
Chief Compliance Officer	Jim Gentile, 508-368-9384
Medicare Compliance Officer	Lisa Lashbrook, 508-368-9539
Privacy Officer	Kate Sanford, 508-368-9838
Director, Internal Audit and Special Investigation Unit	Velinda Brown, 508-368-9016
Security Officer	Tony Petisce, 508-368-9300
Director, Regulatory Affairs and Compliance	Anna Szymczak, 508-368-9211