



2019 Fallon Health First Tier Entity Annual Assessment Guide

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Introduction

Fallon Health's [First Tier, Downstream, and Related Entities 101 Guide](#) outlines requirements that your organization as a First Tier Entity (FTE) must adhere to, to ensure compliance with Medicare regulations, including Fraud, Waste and Abuse (FWA) and General Compliance training for your staff, exclusion list screening, reporting FWA and compliance concerns to Fallon, utilizing offshore resources, and monitoring and auditing your downstream entities.

On an annual basis, your organization must attest that it is compliant with these requirements. Some years, your organization will be asked to provide evidence that each requirement has been satisfied. Your organization will be told that it has been selected for a document request within the annual attestation notification.

Standards of Conduct and Conflicts of Interest

References: Medicare Managed Care Manual, Chapter 21, §50.1; Prescription Drug Benefit Manual, Chapter 9, §50.1; 42 C.F.R. §§ 422.503(b)(4)(vi)(A), 423.504(b)(4)(vi)(A), 438.230, 457.1233

- 1. FTE has adopted and implemented its own Standards of Conduct** (or similar documents) and written Compliance Policies and Procedures for its board members, employees (including temporary), volunteers/interns, providers, and downstream entities/subcontractors.
 - If “No”, FTE has adopted and implemented the Fallon Health’s Vendor/Supplier Code of Conduct/written Compliance Policies and Procedures for its board members, employees (including temporary), volunteers/interns, providers, and downstream entities/subcontractors.
- 2. FTE distributes its adopted Standards of Conduct** to board members, employees (including temporary), volunteers/interns, providers, and downstream entities/subcontractors **within 90-days** of hire/contracting, and/or upon required updates/mandates and annually thereafter. FTE, in compliance with CMS documentation retention requirements, maintains documentation, distribution and receipt documentation. This information is available for Sponsor access and audit.

Your organization must have policies and procedures in place that govern the delegated function(s) and compliance processes, and it must distribute those policies and procedures within your organization as appropriate. Please note, you must also provide your employees with Standards of Conduct within 90 days of hire or the effective date of contracting, when there are updates to such Standards of Conduct, and annually thereafter.

If you do not have a Standards of Conduct, you may utilize Fallon’s [Vendor and Supplier Code of Conduct](#).

Document request: Code of Conduct

- 3. FTE identifies and addresses conflicts of interest** for board members, employees (including temporary), volunteers/interns, providers, and downstream entities/subcontractors on at least an annual basis and maintains documentation of all conflict of interest questionnaires, responses, and follow-up activities.

FTE’s are required to obtain a conflict of interest statement upon hire or contract and annually thereafter from all of their employees and downstream entities. This statement certifies that the individual or entity is free from any conflict of interest to sufficiently perform their job function or service(s) in support of Fallon Health business.

If you are unsure about any potential conflicts of interest, please consult with your legal counsel.

Document request: Conflict of Interest Policy

Medicare Compliance and Fraud, Waste and Abuse Training

References: Medicare Managed Care Manual, Chapter 21, §50.3; Prescription Drug Benefit Manual, Chapter 9, §50.3; 42 C.F.R. §§ 422.503(b)(4)(vi)(C), 423.504(b)(4)(vi)(C), 438.230

4. **FTE's** board members and applicable employees (including temporary), volunteers/interns, providers, and downstream entities/subcontractors **complete General Compliance Training within 90-days** of hire or contracting and annually thereafter and documentation of completion is maintained by the FTE, per CMS retention requirements and Sponsor accessible for audit.

To comply with this requirement, FDRs must ensure board members and all employees, providers, and downstream entities who work on a Fallon Health Medicare product complete the General Compliance and FWA training via the CMS Medicare Learning Network (MLN) within 90 days of hire or contract and annually thereafter. FDRs must maintain evidence of training completion for ten years. The training is available at: <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-LN/MLNProducts/Downloads/MedCandDGenCompdownload.pdf>.

5. **FTE's** board members and applicable employees (including temporary), volunteers/interns, providers, and downstream entities/subcontractors **complete FWA training within 90-days** of hire or contracting and annually thereafter and documentation of completion is maintained by the FTE, per CMS retention requirements and Sponsor accessible for audit.

To comply with this requirement, FDRs must ensure board members and all employees, providers, and downstream entities who work on a Fallon Health Medicare product complete the General Compliance and FWA training via the CMS Medicare Learning Network (MLN) within 90 days of hire or contract and annually thereafter. FDRs must maintain evidence of training completion for ten years. The training is available at: <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/CombMedCandDFWAdownload.pdf>.

If your organization is enrolled into the Medicare program or has been accredited as a Durable Medical Equipment, Prosthetics, Orthotics, and supplies (DMEPOS), it is deemed to have met the training and educational requirements for fraud, waste, and abuse.

Records Management

References: 42 C.F.R. §§ 422.504(d), 438.230

6. **FTE maintains all records** related to administration or delivery of Part C and/or Part D benefits and including but not limited to: attendance records for General Compliance and FWA Training, Standards of Conduct Training, Compliance Policy Training, and monthly evidence of OIG and GSA/SAM screening records **for a period of 10 years**.

CMS and federal regulations require that all information associated with Medicare Advantage programs must be maintained for at least 10 years. This includes, but is not limited to, training documentation, exclusion screenings, data, and report code.

Document request: Record retention policy or schedule

Reporting

References: Medicare Managed Care Manual, Chapter 21, §50.7.3; Prescription Drug Benefit Manual, Chapter 9, §50.7.3; 42 C.F.R. §§ 422.503(b)(4)(vi)(G), 423.504(b)(4)(vi)(G), 438.230; False Claims Acts (31 U.S.C. §§ 3729-3733)

7. **FTE has a widely publicized system** in place for board members, employees (including temporary), volunteers/interns, providers, and downstream entities/subcontractors **to report compliance questions, concerns, or potential misconduct, and FWA** confidentially and anonymously.

FDRs must have in place a system to report issues of noncompliance and suspected/potential FWA concerns that maintains confidentiality and anonymity, if desired. If you do not already have a mechanism in place, and if the issue impacts Fallon Health, please share and prominently display the Fallon anonymous hotline number, 1-888-203-5295 or visit fallonhealth.org/about-fchp/contact-us.aspx.

Document request: Evidence of organization’s reporting system, e.g., policy, procedure, employee communication

8. **FTE has a non-retaliation (whistle-blower) policy** that is communicated to all employees, temporary employees and downstream entities.

FDRs must have a policy of non-retaliation and non-intimidation for individuals who report issues of noncompliance and suspected/potential FWA concerns when done in good faith.

Document request: Non-retaliation policy

9. **FTE has processes in place to report areas of compliance concern or potential misconduct impacting Fallon Health business** to report to Fallon and/or appropriate law enforcement agency **in a timely manner** in order to ensure timely resolution.

- Please explain how your organization will report issues to Fallon:

Monitoring and Auditing

References: Medicare Managed Care Manual, Chapter 21, §50.6; Prescription Drug Benefit Manual, Chapter 9, §50.6; 42 C.F.R. §§ 422.503(b)(4)(vi)(E), 423.504(b)(4)(vi)(E), 438.230

10. **FTE has an auditing and monitoring program** that addresses functions and services performed as part of the delegated relationship.

FDRs must conduct sufficient oversight (e.g., auditing and monitoring) to test and ensure that your employees and downstream entities are compliant. Your organization must retain evidence of oversight completion, ensure root cause analysis is conducted for any deficiencies, and implement corrective actions or take disciplinary actions such as contract termination, as necessary, to prevent recurrence of noncompliance.

11. **FTE has processes in place to report auditing and monitoring results** to Fallon Health routinely or upon request.

OIG/GSA Exclusion Monitoring

References: Medicare Managed Care Manual, Chapter 21, §50.6; Prescription Drug Benefit Manual, Chapter 9, §50.6; The Social Security Act §1862(e)(1)(B), 42 C.F.R. §§ 422.503(b)(4)(vi)(F), 422.752(a)(8), 423.504(b)(4)(vi)(F), 423.752(a)(6), 438.230, 1001.1901

- 12. FTE screens** all board members, employees (including temporary), volunteers/interns, providers, and downstream entities/subcontractors against the Office of Inspector General (OIG) List of Excluded Individuals and Entities (LEIE) and General Services Administration (GSA) System for Award Management (SAM) **prior to initial hire or contracting and monthly thereafter and maintains evidence** of all screening activities and results.
- 13. FTE immediately removes** any board members, employees (including temporary), volunteers/interns, providers, and downstream entities/subcontractors responsible for the administration or delivery of any Part C and/or Part D benefits **found on the OIG or GSA exclusion lists from any work related** (directly or indirectly) **to federal health care programs, and has a process in place to notify Fallon Health.**

All employees who support the functions delegated to your organization by Fallon and who work on federally funded programs, including Medicare, must not be excluded from participation on the OIG (LEIE) or GSA (EPLS/SAM) lists prior to hire or contract and monthly thereafter. As such you must screen your organization, downstream entities, and employees/contractors, as defined above, on the following lists prior to hire or contract and monthly thereafter at <https://exclusions.oig.hhs.gov/> and <https://www.sam.gov/SAM/pages/public/searchRecords/search.jsf>.

Any identification of excluded entities must be removed from working on the product immediately and reported to Fallon.

Oversight of Downstream Entities

References: Medicare Managed Care Manual, Chapter 21, §50.6 and Chapter 11, §100; Prescription Drug Benefit Manual, Chapter 9, §50.6; 42 C.F.R. §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F), 438.230

Please list all downstream entities that are supporting your organization's contract with Fallon Health or select "Not applicable"

Please provide the names of all current vendors your organization is currently using to fulfil any part of its contract with Fallon Health.

- 14. FTE validates** that downstream entities maintain **Business Associate Agreements.**
- 15. FTE's contracts, and any applicable downstream contracts, contain the CMS required language** as stated in Medicare Managed Care Manual, Chapter 11, §100.
- 16. FTE validates that downstream entities meet the requirements** outlined in this attestation **on an annual basis.**

FDRs are responsible for ensuring your subcontractors and downstream entities meet the same compliance requirements that you, as a First Tier Entity, are required to meet (i.e. outlined in the FDR 101 Guide).

- o If you do not subcontract or delegate any functions, your answer should be "Not Applicable".*

- *If you do sub-delegate any functions delegated to your organization by Fallon, you must provide a comprehensive list of these delegated functions in the field below.*

Offshore Subcontracting

References: 07/23/2007 CMS issued guidance, Sponsor Activities Performed Outside of the United States (Offshore Subcontracting); 2008 Call Letter, Privacy and Security Requirements and MAO Activities Performed Outside the United States on page 36 and Sponsor activities performed outside the United States on page 84; 09/20/2007 CMS issued guidance, Sponsor Activities Performed Outside of the United States (Offshore Subcontracting) Questions & Answers; The Health Insurance Portability and Accountability Act of 1996, 45 CFR Parts 160, 162 and 164

17. FTE offshores protected health information (PHI).

FDRs are required to notify Fallon Health within 30 days of amending a contract with or contracting with an offshore entity that will store or have access to Fallon PHI. Please use submit Fallon's [Offshore Subcontractor Attestation](#) to ComplianceBlast@fallonhealth.org.

Quick Links

Fallon Health's Government Program Vendor Oversight Webpage

fallonhealth.org/en/Government-Programs-Vendors.aspx

Fallon Health's FDR 101 Guide

fallonhealth.org/~media/Files/General/CMSvendors/FDR101.ashx?la=en

Fallon Health's Vendor and Supplier Code of Conduct

fallonhealth.org/~media/Files/General/CMSvendors/VendorCodeOfConduct.ashx?la=en

CMS Medicare Learning Network

<https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNGenInfo/Index.html>

Office of Inspector General Exclusion List

<https://exclusions.oig.hhs.gov/>

Government Services Administration Exclusion List

<https://www.sam.gov/SAM/pages/public/searchRecords/search.jsf>