



First-Tier, Downstream, and Related Entities Compliance Guide

SECTION 1: Overview of This Document

Step 1: Review the [FDR Compliance Guide 2023](#) (this document)

Step 2: Complete the [CMS FWA Annual Training](#)

Step 3: Review our [Code of Conduct](#)

Step 4: Review our [Compliance Program](#)

Step 5: Review our [Fraud, Waste, and Abuse Prevention Policy](#)

Step 6: Review our [Monitoring and Reporting Policy](#)

Step 7: Review our [Responding to Reports of Non-compliance Policy](#)

Step 8: Sign and return the [Annual Attestation](#)

Step 9: Review, sign, and return the [Business Associate Agreement](#)

SECTION 2: Introduction to the Compliance Guide

First-Tier, Downstream, and Related Entities

McGregor depends on you, our contracted providers, and other vendors/contractors, to help us meet the needs of our beneficiaries/participants in accordance with Medicare Advantage (MA)/Part D program requirements. In this capacity, you/your organization is considered a First-Tier, Downstream, or Related Entity (FDR) – individuals or entities to whom McGregor has delegated health care and other

service functions relating to McGregor’s MA/Part D contract with the Centers for Medicare and Medicaid Services (CMS).

FDR’s are vital to the success of McGregor’s programs and services. As such, the purpose of this FDR Compliance Guide is to assist FDRs in understanding and meeting the compliance obligations under its contract(s) with McGregor– applied uniformly to all McGregor entities.

FDR as Defined by CMS

First-Tier Entity – “any party that enters into a written arrangement, acceptable to CMS, with a Medicare Advantage Organization (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, acceptable to CMS, 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:

- (1) “Performs some of the MAO or Part D plan sponsor’s management functions under contract or delegation;
- (2) Furnishes services to Medicare enrollees under an oral or written agreement; or
- (3) 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](#)).

SECTION 3: FDR Compliance Requirements

McGregor’s Commitment to Compliance

McGregor is committed to conducting its business operations in compliance with ethical standards, contractual obligations, applicable state laws, federal laws, regulations, and rules. McGregor’s compliance commitment extends to its FDRs. McGregor is a CMS Contractor. CMS also requires McGregor’s FDRs to fulfill specific Medicare Compliance Program requirements.

You have received this guide because we have identified you as an FDR of McGregor/McGregor PACE.

FDR Compliance Program and Attestation Requirements

Although McGregor contracts with FDRs to assist in providing healthcare and other services for our beneficiaries/participants, we are ultimately responsible for fulfilling the terms and conditions of our contract with CMS and meeting applicable Medicare program requirements.

Compliance Program Requirements

As an FDR, you/your organization must comply with Medicare Compliance Program requirements.

Medicare Compliance Program requirements include, but are not limited to:

- General Compliance and Fraud, Waste, and Abuse (FWA) Training.
- Distribution of Compliance Policies, Procedures, and Standards of Conduct.
- Office of Inspector General (OIG) and the Government Services Administration (GSA) Exclusion.
- Record Accessibility and Preservation.
- Communication and Reporting Mechanisms.
- [Offshore Subcontractors](#)
- Monitoring and Auditing FDRs and Downstream Entities.

Each of these requirements and compliance expectations are described in Section 3 of this document “FDRs – What’s Required and How to Comply.”

Please review Section 3 to confirm you have sufficient internal processes in place to ensure your compliance with the requirements. FDR resources and related documents are included in Section 6 of this document.

FDR Annual Attestation

McGregor will confirm FDR compliance with the Medicare Compliance Program requirements each year. You or an authorized representative from your organization must attest to your compliance with the requirements described in Section 3 of this guide. The authorized representative is an individual who has responsibility directly or indirectly for all employees, contracted entities, and staff, and providers/practitioners – this could be an executive, compliance officer, practice manager or someone in a similar position.

FDRs Failing to Comply

McGregor’s response to noncompliance is handled on a case-by-case basis. Depending on the severity of the noncompliance issue, McGregor may require retraining, development of a corrective action plan, or termination of FDR’s contract.

SECTION 4: FDR’s – What’s Required and How to Comply

General Compliance and FWA Training

CMS Requirement:

General Compliance Training – Sponsors must ensure that general compliance information is communicated to their FDRs. The sponsor’s compliance expectations can be communicated through distribution of the sponsor’s Standards of Conduct and/or compliance policies and procedures to FDRs’ employees. **(Medicare Managed Care Manual, Chapter 21, §50.3.1).**

FWA Training – The sponsor’s employees (including temporary workers and volunteers), and governing body members, as well as FDRs’ employees who are involved in the administration or delivery of Parts C and D benefits must, at a minimum, receive FWA training within 90 days of initial hiring (or contracting in the case of FDRs), and annually thereafter. Sponsors must demonstrate that their employees and FDRs

have fulfilled these training requirements. Examples of proof of training may include copies of sign in sheets, employee attestations and electronic certifications from the employees taking and completing the training. ([Medicare Managed Care Manual, Chapter 21, §50.3.2](#)).

How to be Compliant:

1. Any individuals who work on behalf of McGregor’s Medicare organization must be trained in these two modules within 90 days of initial hire and annually thereafter. However, not all FDR employees need to complete the two training courses.
2. If your entity is enrolled in Part A or B of the Medicare program or through accreditation as the supplier of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS). Then your entity is “deemed” to have met the FWA training requirement. However, completion of the General Compliance is mandatory for your entity.

Distribution of Compliance Policies, Procedures, and Standards of Conduct

CMS Requirement:

To be effective, compliance policies and procedures and Standards of Conduct must be distributed to employees who support the sponsor’s Medicare business. Distribution must occur within 90 days of hire, when there are updates to the policies, and annually thereafter. ([Medicare Managed Care Manual, Chapter 21, §50.1.3](#)).

Policies and Procedures for your review:

1. [Compliance Program](#)
2. [Code of Conduct](#)
3. [Fraud, Waste, and Abuse Prevention Policy](#)
4. [Monitoring and Reporting Policy](#)
5. [Responding to Reports of Non-Compliance Policy](#)

How to be Compliant:

1. If your FDR does not have comparable documentation then download the procedures, policies, and Standards of Conduct (SOC) from the McGregor SharePoint site and distribute to employees within 90 days of initial hire or execution of contract and annually thereafter.
2. If you have comparable policies, procedures, and SOC then distribute to staff members within the noted time limits.

OIG and GSA Exclusion

CMS Requirement:

Sponsors must review the Department of Health and Human Services (DHHS) OIG List of Excluded Individuals and Entities (LEIE list) and the GSA Excluded Parties Lists System (EPLS) prior to the hiring or contracting of any new employee, temporary employee, volunteer, consultant, governing body member, or FDR, and monthly thereafter, to ensure that none of these persons or entities are excluded or become excluded from participation in federal programs. Monthly screening is essential to prevent inappropriate payment to providers, pharmacies, and other entities that have been added to exclusions lists since the

last time the list was checked. ([Medicare Managed Care Manual, Chapter 21, §50.6.8](#)) * Governing body includes any member of the board of directors, key management staff, executive staff, or any major stockholders (5%).

How to be Compliant:

1. Check the two databases prior or at the time of hiring or contracting and monthly thereafter.
2. Document and retain evidence of the OIG and GSA exclusion checks/screens.
3. Immediately, remove an employee or affiliate from work then notify McGregor.

Record Accessibility and Preservation

CMS Requirement:

That first-tier and downstream entities must comply with Medicare laws, regulations, and CMS instructions ([422.504\(i\)\(4\)\(v\)](#)) and agree to audits and inspection by CMS and/or its designees and to cooperate, assist, and provide information as requested, and maintain records a minimum of 10 years. ([Medicare Managed Care Manual, Chapter 11, §100.4](#)).

Sponsors are accountable for maintaining records for a period of 10 years of the time, attendance, topic, certificates of completion (if applicable), and test scores of any tests administered to their employees and must require FDRs to maintain records of the training of the FDRs' employees. ([Medicare Managed Care Manual, Chapter 21, §50.3.2](#))

CMS has the discretionary authority to perform audits under 42 C.F.R. §§422.504(e)(2) and 423.505(e)(2), which specify the right to audit, evaluate, or inspect any books, contracts, medical records, patient care documentation, and other records of sponsors or FDRs that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable under the contract or as the Secretary of Health and Human Services may deem necessary to enforce the contract.

Sponsors and FDRs must provide records to CMS or its designee.

Sponsors should cooperate in allowing access as requested. Failure to do so may result in a referral of the sponsor and/or FDR to law enforcement and/or implementation of other corrective actions, including intermediate sanctioning in line with 42 C.F.R. Part 423 Subpart O. ([Medicare Managed Care Manual, Chapter 21, §50.6.11](#)).

How to be Compliant:

1. Preserve the documentation in a logical and organized manner for accessibility during a CMS or McGregor audit for 10 years or longer.

Communication and Reporting Mechanisms

CMS Requirement:

Sponsors must have a system in place to receive, record, respond to and track compliance questions or reports of suspected or detected noncompliance or potential FWA from employees, members of the governing body, enrollees and FDRs and their employees. Reporting systems must maintain confidentiality (to the greatest extent possible), allow anonymity if desired (e.g., through telephone hotlines or mail drops), and emphasize the sponsor's / FDR's policy of non-intimidation and non-

retaliation for good faith reporting of compliance concerns and participation in the compliance program. FDRs, that partner with multiple sponsors, may train their employees on the FDR's reporting processes including emphasis that reports must be made to the appropriate sponsor. The methods available for reporting compliance or FWA concerns, and the non-retaliation policy must be publicized throughout the sponsor's or FDR's facilities. Sponsors must make the reporting mechanisms user friendly, easy to access and navigate, and available 24 hours a day for employees, members of the governing body, and FDRs. It is best practice for sponsors to establish more than one type of reporting mechanism to account for the differences in ways in which people prefer to communicate or feel comfortable communicating.

[\(Medicare Managed Care Manual, Chapter 21, §50.4.2\)](#)

How to be Compliant:

1. Inform your employees on specific policies such as the False Claims Act.
2. Train employees on the importance of reporting violations of compliance or FWA.
3. Create a reporting mechanism for your organization that is anonymous and does not lead to retaliation; or refer your employees to report compliance issues to McGregor's Hotline. The Hotline number can be found in McGregor's Compliance Guide under the section of Reporting Ethics, Compliance Concerns, and FWA.

Offshore Subcontractors

CMS Requirement:

Sponsors that work with offshore subcontractors (first-tier, downstream and related entities) to perform Medicare-related work that uses beneficiary protected health information (PHI) are requested to provide CMS with specific offshore subcontractor information and complete an attestation regarding protection of beneficiary PHI. [\(CMS Memo dated August 26, 2008: Offshore Subcontractor Module in HPMS\)](#).

How to be Compliant:

1. McGregor requires you to include CMS language (specifically Medicare Part C and D) into any contract with an offshore subcontractor.
2. Perform annual audits (as you would with "typical" downstream entities) on the offshore subcontractor.
3. Complete the Offshore Subcontractor Questions included in the FDR Attestation document.
4. Complete the [Offshore Subcontractor Attestation](#) (where applicable).

Monitoring and Auditing FDRs and Downstream Entities

CMS Requirement:

Sponsors are responsible for the lawful and compliant administration of the Medicare Parts C and D benefits under their contracts with CMS, regardless of whether the sponsor has delegated some of that responsibility to FDRs. The sponsor must develop a strategy to monitor and audit its first-tier entities to ensure that they maintain compliance with all applicable laws and regulations, and to ensure that the first-tier entities are monitoring the compliance of the entities with which they contract (the sponsors' "downstream" entities). Monitoring of first-tier entities for compliance program requirements must include an evaluation to confirm that the first-tier entities are applying appropriate compliance program requirements to downstream entities with which the first-tier contracts. [\(Medicare Managed Care Manual, Chapter 21, §50.6.6\)](#).

How to be Compliant:

1. Does your organization contract with another organization outside of McGregor to fulfill McGregor's Medicare business functions? If yes, they are a downstream entity to McGregor.
2. First-Tier (your entity) is responsible for the compliance of McGregor's downstream entities. Therefore, you must dispense any documents or knowledge to certify those entities are compliant with CMS. Monitoring and Auditing are required with evidence retained.
3. Create a procedure for monitoring downstream entities regularly.
- 4.

SECTION 5: Monitoring and Auditing FDR's

Monitoring FDRs

McGregor monitors FDRs for all services or responsibilities delegated by McGregor, and monitors FDR performance through periodic reports (monthly, quarterly, etc.). FDRs must routinely monitor their Downstream Entities if they are performing services for any McGregor line of business.

Auditing FDRs

McGregor periodically audits its FDRs; CMS has the discretionary authority to perform audits under 42 C.F.R. §§422.504(e)(2) and 423.505(e)(2). FDRs should be prepared to cooperate in allowing access to physical locations and records as requested. Failure to do so may result in a referral of McGregor or you/your organization to law enforcement and/or immediate corrective actions, including intermediate sanctioning in line with 42 C.F.R. Part 423 Subpart O.

Below you will find a list of potential documents that may be requested of your entity.

Evidence or documentation of:

1. Auditing of downstream entities.
2. CAPs for downstream entities.
3. Distribution of policies, procedures, and SOC.
4. Education of reporting ethics, compliance violations, and FWA.
5. Exclusion checks/screens.
6. General compliance training.
7. FWA training.
8. Monitoring of downstream entities.
9. Offshore subcontracting information.

SECTION 6: How to Report Compliance and FWA Issues

Reporting is key in the prevention, detection, and correction of program noncompliance and FWA. McGregor protects any individual or organization who reports a legitimate concern in good faith from retaliation and intimidation. FDRs who fail to report a possible violation or suspected FWA that you knew about could result in investigation of you and/or your organization and potentially disciplinary action. To

the extent possible, reports are kept confidential. Anonymous reporting is available through the Compliance Hotline.

Reports can be made to McGregor PACE by doing any of the following:

- Call the Anonymous Compliance Hotline at: (216) 337-4893
- Email: compliance@mcgregoramasa.org
- Write to McGregor's Compliance Officer at:
McGregor
Attn: Compliance Department
14900 Private Drive
Cleveland, Ohio 44112

The Compliance Officer is responsible for ensuring that FDRs continue to meet the CMS and contractual obligations on an ongoing basis and is happy to answer all your questions and concerns regarding your FDR status and/or compliance requirements. Your inquiries are welcome at (216) 268-8402.

SECTION 7: CMS Online Resources

CMS provides a wealth of Medicare related educational tools and other resources at www.cms.gov. Below are links to the tools/resources applicable to FDR requirements referenced in this FDR Compliance Guide:

- [CMS Medicare Learning Network](#)
- [Office of Inspector General, Exclusion Database \(OIG LEIE\)](#)
- [General Services Administration, System for Award Management \(GSA SAM\)](#)
- [Medicare Managed Care Manual](#) (See Chapters 11 and 21)