



First-Tier, Downstream, or Related (FDR) Entity Compliance Program Attestation

As part of an effective compliance program, the Centers for Medicare and Medicaid Services (CMS) and other federal and state regulators require Medicare Advantage Organizations (MAOs/Sponsors) to communicate and monitor specific compliance and fraud, waste and abuse (FWA) requirements to its First Tier, Downstream and Related entities (FDRs), including guidance set forth in Title 42 of the Code of Federal Regulations, Parts 422 and 423 and sub-regulatory guidance published in both Pub. 100-16, Medicare Managed Care Manual Chapter 21, and in Pub. 100-18, Medicare Prescription Drug Benefit Manual Chapter 9. While a Medicare Sponsor may contract with FDRs to perform certain functions on its behalf, the Sponsor maintains ultimate responsibility for fulfilling the terms and conditions of its contract with CMS and for meeting the Medicare program requirements, including ensuring that FDRs are in compliance with all applicable laws, rules and regulations with respect to delegated responsibilities.

This Attestation Form is to facilitate the oversight and monitoring for FDR compliance with the CMS and other federal and state regulators program requirements. We are asking our First Tier Entities to complete and sign this Attestation Form. This Attestation Form must be signed by an individual with the authority to attest to the accuracy and completeness of the information provided.

Please select all the statement(s) that apply to your organization.

Standards of Conduct & Written Policies and Procedures

I confirm that our organization has implemented its own Standards of Conduct and written Compliance Policies & Procedures

I confirm that our organization has adopted and implemented Leon Health’s Code of Conduct and written Compliance Policies & Procedures

Other (please describe): _____

General Compliance and Fraud, Waste, and Abuse (FWA) Trainings

I confirm that our organization uses its own Compliance/FWA Trainings

I confirm that our organization has adopted Leon Health’s Compliance/FWA Trainings

I confirm that our organization uses CMS’s Web-Based Training Compliance/FWA Training

Other (please describe): _____



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Off-shore subcontracting- Medicare Advantage Organizations and Part D Sponsors

CMS requires organizations with offshore subcontractor* arrangements, ensure the CMS Health Plan Management System (HPMS) Offshore Subcontracting module is up to date regarding the functions offshore subcontractors perform within 30 calendar days of signing an offshore contract. As such, if your entity is going to or has subcontracted with an offshore subcontractor, you must notify Leon Health immediately.

Does your entity utilize Offshore* Subcontractors?

Yes No

If you selected “Yes”, you **must** complete an offshore attestation (Please see Attachment below “Offshore Attestation”)

* Offshore subcontractor is defined as a first tier/downstream/related entity located outside of the one of the fifty U.S. states, the District of Columbia, or one of the United States Territories (American Samoa, Guam, Northern Marianas, Puerto Rico, and Virgin Islands).

This attestation confirms your commitment to comply with the following CMS requirements:

Distribution of Standards of Conduct and Compliance Policies & Procedures:

Chapter 21 of the Medicare Managed Care Manual/Chapter 9 of the Prescription Drug Benefit Manual, §50.1 - 42 C.F.R. §§ 422.503(b)(4)(vi)(A), 423.504(b)(4)(vi)(A)

- Our organization has Standards of Conduct that explain describe our expectations that all employees conduct themselves in an ethical manner; that issues of noncompliance and potential FWA are reported through appropriate mechanisms; and that reported issues will be addressed and corrected.
- Our organization has Compliance Program Policies & Procedures that describe the operation of the compliance program. Compliance policies may address issues such as sponsors’ compliance reporting structure, compliance and FWA training requirements, the operation of the hotline or other reporting mechanisms, and how suspected, detected or reported compliance and potential FWA issues are investigated and addressed and remediated.
- Our organization ensures that the Code of Conduct and Compliance Policies & Procedures are distributed to employees within ninety (90) days of hire, upon revision and annually thereafter.
- Our organization retains evidence of Code of Conduct and Compliance Policies & Procedures Distribution



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General Compliance and Fraud, Waste and Abuse (FWA) and Training and Education Requirements:

Chapter 21 of the Medicare Managed Care Manual/Chapter 9 of the Prescription Drug Benefit Manual, §50.3 - 42 C.F.R. §§ 422.503(b)(4)(vi)(C), 423.504(b)(4)(vi)(C)

- Our organization requires employees (including temporary workers and volunteers), and governing body members to complete General Compliance & FWA Training within ninety (90) days of hire or contracting and annually thereafter.
- Our organization retains evidence of training completion.

OIG/GSA Exclusion Monitoring:

Chapter 21 of the Medicare Managed Care Manual/Chapter 9 of the Prescription Drug Benefit Manual, §50.6 - The 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), 1001.190

- Our organization conducts a review of the 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.

Attestation of Medicare Compliance Program Requirements for FDRs:

By signing this annual attestation, you are confirming that you reviewed and understood the Medicare Compliance Program Requirement materials shared & that the statements contained within the attestation are factual and correct to the best of your knowledge.

Any violations of the Medicare Part C and D Requirements outlined in the Code of Federal Regulations, Parts 422 and 423, as well as the Medicare Prescription Drug Benefit Manual Chapter 9 and the Medicare Managed Care Manual Chapter 21, is a violation of your contract with Leon Health and may result in corrective actions, up to and including contract termination.

FDR Compliance Program Attestation (Please complete below)

Name of Organization: _____

Signature: _____ Date: _____

Print Name: _____

Title: _____

Please Return by e-mail to: *compliance@leonhealth.com*



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Attachment I

Offshore Attestation

Part I. Offshore Subcontractor Information

Offshore Subcontractor Name: _____

Offshore Subcontractor Country: _____

Offshore Subcontractor Address: _____

Offshore Subcontractor Function: _____

Proposed or Actual Effective Date for offshore subcontractor: _____

Part II. Precautions for Protected Health Information

Description of the PHI that will be provided to the Offshore Subcontractor:

Discussion of why providing PHI is necessary to accomplish the Offshore Subcontractor objectives:

Description of alternatives considered to avoid providing PHI, and why each alternative was rejected:

Part I. Attestation of Safeguards to Protect Beneficiary Information in the Offshore Subcontract

Offshore subcontracting arrangement has policies and procedures in place to ensure that the Medicare beneficiary protected health information (PHI) and other personal information remains secure.

Yes No

Offshore subcontracting arrangement prohibits subcontractor's access to Medicare data not associated with the sponsor's contract with the offshore subcontractor.

Yes No

Offshore subcontracting arrangement has policies and procedures in place that allow for immediate termination of the subcontract upon discovery of a significant security breach.



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Yes No

Offshore subcontracting arrangement includes all required Medicare Part C and D language (e.g., record retention requirements, compliance with all Medicare Part C and D requirements, etc.)

Yes No

Part II. Attestation of Audit Requirements to Ensure Protection of PHI

Organization will conduct an annual audit of the offshore subcontractor.

Yes No

Audit results will be used by the Organization to evaluate the continuation of its relationship with the offshore subcontractor.

Yes No

Organization agrees to share offshore subcontractor's audit results with CMS, upon request.

Yes No

Name of Organization: _____

Signature: _____ Date: _____

Print Name: _____

Title: _____