

First Tier Entity Attestation 2017

Medicare Advantage Organization (Sponsor) Compliance Program

10/19/2017

As part of an effective compliance program, the Centers for Medicare and Medicaid Services (CMS) and other federal and state regulators require our Medicare Advantage Organizations (MAO/Sponsor) communicate and monitor specific compliance and fraud, waste and abuse (FWA) requirements to our 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. 100-18, Medicare Prescription Drug Benefit Manual Chapter 9, and in Pub. 100-16, Medicare Managed Care Manual Chapter 21. While a Medicare Sponsor may contract with FDRs to perform certain functions¹ 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, laws, rules and regulations. 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 submit the completed Attestation Form by **11/16/2017.**

Timely submission is a condition of continued FDR and Sponsor contracting.

Note: Medicare Advantage Organizations (Sponsors) that agreed to collaborate and use the same attestation form are noted in Resource 1- "Sponsor Participant List" which is posted on the following ICE website: [ICE FDR Documents](#).

The Industry Collaboration Effort, Inc. (ICE) collaboration is seeking to complete this process electronically next year in order to further reduce the administrative burden.

¹ For example: 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; and Health care services. [Chapter 21, Section 40].



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Attestation Form Submission Instructions

Please respond “yes” or “no” to the questions below. If the response is “no”, provide an explanation and a corrective action plan to the Sponsor in **Section IX**. Submit the completed, signed attestation by **11/16/2017**. The completed Attestation Form may be submitted via hard copy USPS mail or .pdf document scanned and e-mailed to:

Molina Healthcare Medicare Compliance
Attn: Joanne Valenzuela
200 Oceangate, Suite 100 (WTC 9)
Long Beach, CA, 90802

MDO@MolinaHealthcare.com

Attachment A - Offshore Subcontracting Attestation

Resources: [ICE FDR Documents](#)

Resource 1- Sponsor Participant List (Industry Collaboration information and Contacts)

Resource 2- CMS Fraud Waste Abuse Training Information

First Tier Entity Attestation 2017**Medicare Advantage Organization (Sponsor) Compliance Program****I. Standards of Conduct and Conflicts of Interest:**

- Chapter 9 of the Prescription Drug Benefit Manual, §50.1
- Chapter 21 of the Medicare Managed Care Manual, §50.1
- 42 C.F.R. §§ 422.503(b)(4)(vi)(A), 423.504(b)(4)(vi)(A)
- 42 C.F.R. §§ 438.230, 457.1233
- Deficit Reduction Act of 2005

- a. First tier entity has **adopted and implemented its own** Standards of Conduct (or similar documents) and written Compliance Policies and Procedures for its board members, employees, temporary employees, volunteers/interns, consultants, contractors and downstream entities, sub-contractors.

Yes No

If no response:

First tier entity has **adopted and implemented the Sponsor's** Standards of Conduct/written Compliance Policies and Procedures for its board members, employees, temporary employees, volunteers/interns, consultants, contractors and downstream entities, sub-contractors.

Yes No

- b. First tier entity **distributes** its adopted Standards of Conduct to board members, employees, temporary employees, volunteers/interns, consultants, contractors and downstream entities, sub-contractors within **90-days** of hire/contracting; and/or upon required updates/mandates; and annually thereafter. First tier entity, in compliance with CMS documentation retention requirements, maintains documentation, distribution and receipt documentation. This information would be available for Sponsor access and audit.

Yes No

- c. First tier entity **identifies and addresses conflicts of interest** for board members, employees, temporary employees, volunteers/interns, consultants, contractors and downstream entities on at least an annual basis and maintains documentation of all conflict of interest questionnaires, responses, and follow-up activities.

Yes No

II. General Compliance and Fraud, Waste and Abuse (FWA) Training:

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

- d. First tier entity board members, employees, temporary employees, volunteers/interns, contractors and downstream entities complete CMS Medicare Parts C and D General Compliance Training **Web-Based Training (WBT)** Course within **90-days** of hire or contracting and annually thereafter and documentation of completion is maintained by the First tier entity, per CMS retention requirements and Sponsor accessible for audit.

Yes No



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- e. First tier entity board members, employees, temporary employees, volunteers/interns, contractors and downstream entities complete the CMS Combating Medicare Parts C and D Fraud, Waste, and Abuse WBT Course or download PDF version within **90-days** of hire or contracting and annually thereafter and documentation of completion is maintained by the First-tier entity, per CMS retention requirements and Sponsor accessible for audit.

Yes No

CMS Free WBTs located at:

Medicare Parts C and D General Compliance Training:

<https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/MedCandDGenCompdownload.pdf>

Combating Medicare Parts C and D Fraud, Waste, and Abuse:

<https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/CombMedCandDFWAdownload.pdf>

Resource 2- “CMS Fraud Waste Abuse Training Information” document located at:

[ICE FDR Documents](#)

III. Records Management

- 42 CFR 422.504 (d), 438.230

- f. First tier entity 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 Fraud, Waste and Abuse Training, Standards of Conduct Training, Compliance Policy Training, and monthly evidence of OIG and GSA/SAM screening records for a period of 10 years.

Yes No

IV. Reporting

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

- g. First tier entity has a widely publicized system in place for employees, temporary employees and downstream entities to report compliance questions, concerns, or potential misconduct, and FWA confidentially and anonymously.

Yes No

- h. First tier entity has a non-retaliation policy that is communicated to all employees, temporary employees and downstream entities.

Yes No



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- i. First tier entity has processes in place to ensure compliance concerns or potential misconduct are reported to the Sponsor and/or appropriate law enforcement agency in a timely manner in order to ensure timely resolution.
- Yes No

V. **Monitoring and Auditing**

- Chapter 21 of the Medicare Managed Care Manual §50.6
 - Chapter 9 of the Prescription Drug Benefit Manual, §50.6
 - 42 C.F.R. §§ 422.503(b)(4)(vi)(E), 423.504(b)(4)(vi)(E), 438.230
- j. First tier entity has an auditing and monitoring program that addresses functions and services performed as part of the delegated relationship.
- Yes No
- k. First tier entity has processes in place to report auditing and monitoring results to the Sponsor routinely or upon request.
- Yes No

VI. **OIG/GSA Exclusion Monitoring:**

- Chapter 9 of the Prescription Drug Benefit Manual, §50.6
 - Chapter 21 of the Medicare Managed Care 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), 1001.1901, 438.230
 - For Medicaid Health Sponsors, some states require you also check state exclusion lists, as applicable
- l. First tier entity is **not** currently excluded from participation in any federal healthcare programs.
- Not Currently Excluded Currently Excluded
- m. First tier entity screens all board members, employees, temporary employees, volunteers/interns, consultants, contractors and downstream entities against the Office of Inspector General (OIG) List of Excluded Individuals and Entities (LEIE) and General Services Administration (GSA) System for Award Management (SAM) upon initial hire or contracting and at least monthly thereafter and maintains evidence of all screening activities and results.
- Yes No
- n. First tier entity immediately removes any board members, employees, subcontractors, volunteers/interns, consultants, and downstream entities 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 notifies the Sponsor.
- Yes No



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VII. Oversight of Downstream Entities

- Chapter 9 of the Prescription Drug Benefit Manual, §50.6
 - Chapter 21 of the Medicare Managed Care Manual, §50.6
 - 42 C.F.R. §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F), 438.230
 - Chapter 11 of the Medicare Managed Care Manual, §100
- o. First tier entity validates that downstream entities maintain Business Associate Agreements (when applicable).
- Yes No
- p. First tier entity and downstream contract contain required CMS language as stated in Chapter 11 of the Medicare Managed Care Manual, §100.
- Yes No
- q. First tier entity validates that downstream entities meet the requirements outlined in this attestation on an annual basis.
- Yes No

VIII. Offshore Subcontracting

- Health Insurance Portability and Accountability Act of 1996, 45 CFR Parts 160, 162 and 164
 - CMS issued guidance 08/15/2006 and 07/23/2007; and CMS 2008 Call Letter
- r. If Contractor offshores any **protected health information** (PHI) (guidance provided above), Contractor should complete **Attachment A** within 30-days of entering into or amending any agreement with an Offshore Subcontractor.

Please check one of the following:

- Contractor does not offshore any protected health information.
- Contractor does offshore any protected health information. (Complete Attachment A)

Attachment A should be completed if this information has not been previously provided to the Sponsor and submitted with this Attestation.

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IX. Comments

If there is a “No” response to any of the questions above, please use the space below to provide a corrective action plan to address each instance of non-compliance. If corrective action plan is required, I attest that actions will be completed to remediate in 30 days from the attestation signature date below.

Corrective Action Description:

I attest that the answers provided are complete and accurate to the best of my knowledge and that documentation to support the responses will be made available to the Sponsor or CMS upon request, and understand that the Sponsor may conduct an audit to confirm the attestations (with at least 30 days’ notice).

If a corrective action plan is required, I attest that the actions will be completed in 30 days from the date listed below to remediate attestation gaps.

Organization Name:

Name of Person Completing Form:

Title:

Email Address:

Telephone Number:

Signature:

Date:

Attachment A



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Complete Attachment A if Contractor offshores any protected health information.

NAME OF ENTITY:
Please enter your name, your title and the date that you completed this attestation:
Name:
Title:
Signature:
Date:



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<p align="center">Do You Utilize Offshore Subcontractors? *</p> <p>* CMS Defines an Offshore Subcontractor As: The term “subcontractor” refers to any organization that a Medicare Advantage Organization or Part D Sponsor contracts with to fulfill or help fulfill requirements in their Part C and/or Part D contracts. Subcontractors include all first tier, downstream, and/or related entities. The term “offshore” refers to any country that is not one of the fifty United States or one of the United States Territories (American Samoa, Guam, Northern Marianas, Puerto Rico, and Virgin Islands). Examples of countries that meet the definition of “offshore” include Mexico, Canada, India, Germany, and Japan. Subcontractors that are considered offshore can be either American-owned companies with certain portions of their operations performed outside of the United States or foreign-owned companies with their operations performed outside of the United States. Offshore subcontractors provide services that are performed by workers located <u>in</u> offshore countries, regardless of whether the workers are employees of American or foreign companies.</p>	
<p>We engage in offshore subcontracting that involves receiving, processing, transferring, handling, storing, or accessing Personal Health Information (PHI).</p> <p>*If YES, continue completing the form below.</p> <p>Please return a copy to:</p> <p align="center">Molina Healthcare Medicare Compliance Attn: Joanne Valenzuela 200 Oceangate, Suite 100 (WTC 9) Long Beach, CA, 90802</p> <p>** If NO, the survey is complete. Remember- if a new offshore subcontractor is added, the full document must be completed and sent to the MAO, and address on page one.</p>	

Offshore Subcontracting Attestation - Attachment A

Part I. Offshore Subcontractor Information	
Offshore Subcontractor Name:	
Offshore Subcontractor Country:	
Offshore Subcontractor Address:	



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<p>Describe Offshore Subcontractor Functions:</p>	
<p>State Proposed or Actual Effective Date for Offshore Subcontractor: (MONTH DAY, YEAR: Example January 15, 2017)</p>	

<p>Part II. Precautions for Protected Health Information (PHI)</p>	
<p>Describe the PHI that will be provided to the Offshore Subcontractor:</p>	
<p>Discuss why providing PHI is necessary to accomplish the Offshore Subcontractor objectives:</p>	
<p>Describe alternatives considered to avoid providing PHI, and why each alternative was rejected:</p>	

Offshore Subcontracting Attestation- Attachment A

<p>Part I. Attestation of Safeguards to Protect Beneficiary Information in the Offshore Subcontract</p>		
<p>Item</p>	<p>Attestation</p>	<p>Response Yes or No</p>
<p>I.1.</p>	<p>Offshore subcontracting arrangement has policies and procedures in place to ensure that Medicare beneficiary protected health information (PHI) and other personal information remains secure.</p>	



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I.2.	Offshore subcontracting arrangement prohibits subcontractor's access to Medicare data not associated with the Sponsor's contract with the offshore subcontractor.	
I.3.	Offshore subcontracting arrangement has policies and procedures in place that allow for immediate termination of the subcontract upon discovery of a significant security breach.	
I.4.	Offshore subcontracting arrangement includes all required Medicare Parts C & D language (e.g., record retention requirements, compliance with all Medicare Parts C & D requirements, etc.)	

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

Item	Attestation	Response Yes or No
II.1.	Organization will conduct an annual audit of the offshore subcontractor.	
II.2.	Audit results will be used by the Organization to evaluate the continuation of its relationship with the offshore subcontractor.	
II.3.	Organization agrees to share offshore subcontractor's audit results with CMS, upon request.	