**SAMPLE Downstream and Related Entity Annual Assessment**

As part of an effective compliance program, the Centers for Medicare & Medicaid Services (CMS) requires Medicare Advantage plans to ensure that any FDRs to which the provision of administrative or health care services are delegated are also in compliance with applicable laws and regulations. This attestation confirms your commitment to comply with Medicare program requirements. Requirements are listed below and apply to all services your organization as a Downstream Entity of {FIRST TIER ENTITY} provide to Medicare beneficiaries. The requirements also apply to any of the Downstream Entities[[1]](#endnote-1)you use to provide services to Medicare beneficiaries.

# **Policies, procedures and standards of conduct**

*References: Medicare Managed Care Manual, Chapter 21, §50.1;1; 42 C.F.R. §§ 422.503(b)(4)(vi)(A), 438.230,457.1233*

1. **Downstream 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’, **Downstream Entity has adopted and implemented {insert FTE} Code 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

1. **Downstream Entity distributes its adopted Standards of Conduc**t 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. Downstream Entity, in compliance with CMS documentation retention requirements, maintains documentation, distribution and receipt documentation. This information is available for Sponsor access and audit.

Yes   
 No

# **Records management**

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

1. **Downstream 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 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.

Yes   
 No

# **Reporting**

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

1. **Downstream 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

1. **Downstream Entity has processes in place to report areas of compliance concern or potential misconduct impacting {insert FTE} business** to report to {insert FTE} and/or appropriate law enforcement agency **in a timely manner** in order to ensure timely resolution.

Yes   
 No

# **Monitoring and auditing**

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

1. **Downstream Entity has an auditing and monitoring program** that addresses functions and services performed as part of the delegated relationship.

Yes   
 No

Not applicable, Downstream Entity does not have downstream contracts.

1. **Downstream Entity has processes in place to report auditing and monitoring results** to FTE routinely or upon request.

Yes   
 No

Not applicable, Downstream Entity does not have downstream contracts.

# **OIG/GSA Exclusion Monitoring**

*References: Medicare Managed Care Manual, Chapter 21, §50.6; The Social Security Act §1862(e)(1)(B),42 C.F.R. §§ 422.503(b)(4)(vi)(F),422.752(a)(8)*

1. **Downstream 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) **prior to initial hire or contracting and monthly thereafter and maintains evidence** of all screening activities and results.

Yes   
 No

1. **Downstream 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 has a process in place to notify FTE**.

Yes   
 No

# **Oversight of downstream entities**

*References: Medicare Managed Care Manual, Chapter 21, §50.6 and Chapter 11, §100; 42 C.F.R. §§ 422.503(b)(4)(vi)(F),438.23*

1. **Downstream Entity validates** that downstream entities maintain **Business Associate Agreements**.

Yes  
 No

Not applicable, Downstream Entity does not have downstream contracts.

1. **Downstream Entity’s contracts, and any applicable downstream contracts, contain the CMS required language** as stated in Medicare Managed Care Manual, Chapter 11, §100.

Yes   
 No

Not applicable, Downstream Entity does not have downstream contracts.

1. **Downstream Entity validates that downstream entities meet the requirements** outlined in this attestation **on an annual basis**.

Yes  
 No

Not applicable, Downstream Entity does not have downstream contracts.

# **Offshore resources**

*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*

1. **Downstream Entity offshores any protected health information (PHI)**.

Yes, Downstream Entity does offshore PHI  
 No, Downstream Entitydoes not offshore PHI

If ‘Yes’ **and** information has not been previously provided, please complete the Offshore Subcontract Attestation 30 days of entering into or amending any agreement with an Offshore Subcontractor.

# **Comments**

If there is a ‘**No**’ in the responses provided above, please provide your organization’s action plan to address each instance of potential non-compliance. {FIRST TIER ENTITY} requires that all deficiencies be addressed or have a corrective action plan in place to appropriately remediate any attestation gaps. If the deficiencies are not addressed {FIRST TIER ENTITY} reserves the right to discontinue the contracting process or terminate the contract.

Action plan(s):

1. # **Attestation**

   By checking this box, you confirm that you are authorized to attest to your organization’s adherence with specific Medicare regulatory requirements.

   All fields are required.

   |  |  |  |  |
   | --- | --- | --- | --- |
   | First name: | | Last Name: | |
   | Title: | | | |
   | Company: | | | |
   | Address: | | | |
   | Address Line 2 (if applicable): | | | |
   | City: | State: | | ZIP: |
   | Phone number: | | | |
   | Email: | | | |

   [↑](#endnote-ref-1)