**First Tier, Downstream and Related Entity Annual Assessment**

As part of an effective compliance program, the Centers for Medicare and 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 the Centers for Medicare & Medicaid Services (“CMS”) requirements. These requirements are listed below and apply to all services your organization, as Amplifon Hearing Health Care’s FDR, provide for Amplifon Hearing Health Care patients. The requirements also apply to any of the Downstream Entities[[1]](#endnote-1) you use to provide service for Amplifon Hearing Health Care’s patients.

**Please submit the completed assessment by October 31, 2019.**

**CODE 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 the Amplifon’s 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 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. 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 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**.

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 Amplifon business** to report the Amplifon 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 Amplifon 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 Amplifon**.

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

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 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*

1. **DOWNSTREAM ENTITY offshores any protected health information (PHI)**.

Yes, DOWNSTREAM ENTITY does offshore PHI  
 No, DOWNSTREAM ENTITY does 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. Amplifon 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 Amplifon reserves the right to discontinue the contracting process or terminate the contract.

Action plan(s):



**ATTESTATION**

I attest that the responses provided in this annual performance questionnaire are correct to the best of my knowledge.

Organization Name:

Authorized Signatory Name:

Authorized Signatory Title:

Signature:

Date:

1. [↑](#endnote-ref-1)