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 8/31/20.**

# Code of Conduct

***About this section***

*Your organization must have policies and procedures in place that govern the delegated function(s) and compliance processes, and it must distribute those policies and procedures within your organization as appropriate. Please note, you must also provide your employees with Standards of Conduct within 90 days of hire or the effective date of contracting, when there are updates to such Standards of Conduct, and annually thereafter.*

*If the employee is a solo provider, utilizing AHHC materials is sufficient.*

*If you do not have a Standards of Conduct, you may utilize Amplifon Hearing Healthcare Documents, which are located on the AmplifonUSA website.*

*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

***About this section***

*CMS and federal regulations require that all information associated with Medicare Advantage programs must be maintained for at least 10 years. This includes, but is not limited to, training documentation, exclusion screenings, data, and report code.*

*Downstream entities could demonstrate compliance with this requirement by having a Record retention policy or schedule.*

*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

***About this section***

*FDRs must have in place a system to report issues of noncompliance and suspected/potential FWA concerns that maintains confidentiality and anonymity, if desired. If you do not already have a mechanism in place, and if the issue impacts AHHC, please share and prominently display the Amplifon hotline number, 1-800-234-9134, or compliancedept@amplifon.com.*

*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

***About this section***

*If a downstream entity of AHHC utilizes another service through which to deliver* ***care****, this organization would be considered a downstream entity of theirs. For providers who are solo practitioners, they are the end of the downstream entity chain, and should select Not Applicable for questions #6 & #7.*

*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

***About this section***

*All employees who support the functions delegated to your organization by Amplifon Hearing Health Care and who work on federally funded programs, in*

*cluding Medicare, must not be excluded from participation on the OIG (LEIE) or GSA (EPLS/SAM) lists prior to hire or contract and monthly thereafter. As such you must screen your organization, downstream entities, and employees/contractors, as defined above, on the following lists prior to hire or contract and monthly thereafter at https://exclusions.oig.hhs.gov/ and* [*https://www.sam.gov/SAM/pages/public/searchRecords/search.jsf*](https://www.sam.gov/SAM/pages/public/searchRecords/search.jsf)*.*

*Basically, this is meant to ensure that the downstream entity has a process in place to determine whether any individual working within their organization is prohibited from participating in the Medicare program.*

*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

***About this section***

*A downstream entity is an organization that is used by the provider to complete the work that is part of the contract between AHHC & the provider. For example, AHHC contracts with Audiologists to deliver medical care to AHHC members. If the Audiologist is the only person providing the service to the member on behalf of AHHC, they do not have any downstream entities. However, if they use another provider/organization/entity to deliver care, that provider/organization/entity would be considered to be the downstream entity.*

*If they are using a downstream entity, they need to ensure that the contract with the downstream entity complies with Medicare (#11) and they need to confirm the downstream entity can meet the requirements outlined in this attestation (#12).*

*Note: many providers will* ***not*** *have any downstream entities. They would then check Not Applicable to the above questions.*

*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 Subcontracting

***About this section***

*This is getting at how the recipient of the attestation stores/manages their PHI. If PHI is managed through a paper process, they would check* ***No****. IF PHI is managed electronically, they need to understand whether the entity that manages their PHI does so within the US, or if it is outside of the US (Offshore). If they do not know this information, they can obtain it by asking their contact/sales rep. where the servers for their software is.*

*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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*.*

Frequently Asked Questions

1. **What is this attestation?**
   1. The compliance attestation is a requirement from the Centers for Medicare & Medicaid (CMS). It is intended to ensure that any provider who is eligible to provide services to a Medicare patient, is compliant with Medicare program requirements.
2. **Why do I have to complete this?**
   1. You have received this attestation because you (or a member of your staff) is eligible to provide care to Medicare patients.
3. **What if I do not currently see Medicare or Medicaid patients?**
   1. Due to your contract with Amplifon Hearing Health Care, it is possible that a patient who is a member of a Medicare Advantage plan may be referred to you for care. To minimize any delay in the referral process, it is imperative that we obtain a completed attestation ahead of time to ensure timely service for the customer.
4. **According to the Centers for Medicare & Medicaid, what is a First-Tier, Downstream or Related Entity?**
   1. ***First Tier Entity*** is any party that enters into a written arrangement, acceptable to CMS, with an 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).
   2. ***Downstream Entity*** is 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).
   3. ***Related Entity*** means any entity that is related to an MAO or Part D sponsor by common ownership or control and
      1. (1) Performs some of the MAO or Part D plan sponsor’s management functions under contract or delegation;
      2. (2) Furnishes services to Medicare enrollees under an oral or written agreement; or
      3. (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).
5. **Do I have to complete the training listed?**
   1. CMS no longer requires annual completion of Medicare Parts C&D, or Fraud, Waste and Abuse training. We have included links to this training on the Amplifon USA page as an educational resource for you/your team if interested.

1. [↑](#endnote-ref-1)