

AMPLIFON COMPLIANCE PROGRAM POLICY

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DEPARTMENT: COMPLIANCE	EFFECTIVE DATE: OCTOBER 2020
RESPONSIBLE PARTY: COMPLIANCE MANAGER	LAST REVISED: MARCH 2023
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Purpose

The purpose of this Policy is to establish the parameters of Amplifon's Compliance Program. The goal of Amplifon's Compliance Program is to ensure compliance with all applicable laws and regulations, and should aim to prevent, detect, and correct fraud, waste & abuse.

Scope

This Policy applies to all Amplifon Americas Employees, Contractors, and Board Members.

Key Terms

Please see the Compliance Policy Definitions.

Policy

Amplifon is committed to compliance with laws and regulations it is subject to, including participation in government funded healthcare programs. Amplifon's compliance program consists of compliance elements aimed at fostering a culture of prevention, early detection and remediation of conduct that does not conform with applicable laws, organizational policy, or Amplifon's Code of Ethics. The Compliance Program facilitates adherence to Medicare managed care compliance requirements, as well as meets the criteria set forth by the United States Sentencing Commissions Guidelines.

1. Written Policies, Procedures & Code of Ethics

Amplifon's Written Policies, Procedures, and Code of Ethics reflect the organization's commitment to comply with all applicable federal and state standards, including, among others, Medicare Part C statutes, regulations and program manuals, the federal and state False Claims Acts and Anti-Kickback Statutes, the Health Insurance Portability and Accountability Act (HIPAA) and anticorruption and consumer-protection laws and regulations.

Amplifon will maintain compliance-program policies, procedures and Code of Ethics that demonstrate the following:

- Articulate Amplifon's commitment to comply with all applicable Federal and State standards.
- Describe compliance expectations as embodied in the Code of Ethics.
- Implement the operation of the compliance program.
- Provide guidance for dealing with potential compliance issues.
- Explain how to communicate compliance issues to compliance personnel.
- Describe how compliance issues are investigated and resolved; and
- Include a policy of non-intimidation and non-retaliation for good-faith participation in the compliance program.

Amplifon policies, procedures and Code of Ethics will be distributed:

- To Board members when they are appointed to the Board, when there are material updates, and annually thereafter.
- To new Employees and Contractors when hired or contracted, when there are material updates, and annually thereafter.
- New Employees and Contractors will sign an attestation documenting that the new Employee or Contractor received and understands the Code of Ethics within 90 days of hire/contract and annually thereafter. The attestation will be maintained by Human Resources; and
- Amplifon policies, as well as the Code of Ethics are made available on Amplifon's intranet for Employees and Contractors to access when needed.

Distribution of documents will occur as part of new-hire onboarding or annual training. Amplifon's Compliance department will retain all versions of Compliance written policies, procedures, and Code of Ethics per the Document Retention Schedule Procedure.

2. Compliance Officer, Compliance Committee & High-Level Oversight

Amplifon will have an appointed Compliance Officer and Compliance Committee who will ensure adherence to compliance program requirements, as well as to healthcare, privacy, anti-corruption and consumer-protection laws and regulations.

Compliance Committee

The Compliance Committee is tasked with policy direction and oversight of the Compliance Program. This includes periodic reporting to the Amplifon Americas Board of Directors on activities and status of the compliance program, including issues identified, investigated, and resolved.

Compliance Officer

The Compliance Officer is responsible for day-to-day operations and implementation of the Compliance Program. The Compliance Officer provides reports on the Compliance Program to the Compliance Committee and Amplifon Americas Board of Directors. The Compliance Officer need not await approval of the Board to implement necessary, time-sensitive compliance actions and activities, provided they are reported to the Compliance Committee. The Compliance Officer will ensure that the Amplifon Americas Board of Directors is knowledgeable about the content and operation of the compliance program, allowing the Board to exercise reasonable oversight of the program's implementation and effectiveness.

Board of Directors

Amplifon Americas' Board of Directors must be appropriately engaged in the compliance program, exercising reasonable oversight with respect to its implementation and effectiveness. In general, this means the Board will inquire about the program, require follow-up on issues, and act when necessary. More specifically, the Board will:

- Receive training and education on the structure and operation of the compliance program.
- Remain informed about compliance-program outcomes, including results of internal and external audits as appropriate.
- Remain informed about governmental compliance-enforcement activity.
- Receive regularly scheduled, periodic updates from the Compliance Officer and the Compliance Committee; and
- Review the results of compliance program performance and effectiveness assessments.

Senior Management Involvement in the Compliance Program

Amplifon's CEO and Senior Management will:

- Engage in the compliance program.

- Recognize its importance to Amplifon's success.
- Ensure the Compliance Officer is integrated into the organization; and
- Provide the Compliance Officer the credibility, authority, and resources necessary to operate a robust and effective compliance program.

3. Effective Training & Education

Amplifon will ensure its Employees, Contractors, and Board members receive training and education that will be adequate to ensure compliance with Amplifon's compliance program, relevant laws and regulations, and requirements specific to their job function. Employees that are involved in the administration or delivery of Medicare program benefits will receive Medicare specific Fraud, Waste and Abuse training, as well as Medicare Part C training annually.

Compliance training must occur within 90 days of initial hire and annually thereafter. Additional, specialized or refresher training may be provided on issues posing compliance risks based on an Employee's or Contractor's job function. Amplifon will maintain documentation of completion of required compliance training per the Document Retention Schedule Procedure.

Amplifon will require all employees, board directors, or contractors to sign a confidentiality agreement due to potential work with customers personally identifiable information, personal health information, or other confidential business information.

4. Effective Lines of Communication

Amplifon has established and implemented clear lines of communication that are accessible to all and allow compliance issues to be reported, including a method for anonymous and confidential good faith reporting of potential compliance issues as they are identified. The existing communication channels ensure that Employees, Contractors, and Board Members all have access to report issues of suspected non-compliance directly to the Compliance Officer.

Amplifon has a variety of reporting mechanisms that are always accessible, including email, voicemail (anonymous), a Whistleblowing tool and direct contact to the Compliance department. Amplifon will publish all reporting mechanisms internally and externally, including to Amplifon Hearing Health Care Network providers, and Miracle-Ear clinics & franchisees.

Amplifon will enforce the established non-retaliation policy for all reports are made in good faith.

5. Compliance Program Disciplinary Standards

Amplifon will enforce well-publicized disciplinary standards applicable to any compliance violations, and to encourage good-faith participation in the Compliance Program by all affected individuals. Disciplinary standards related to compliance violations will be publicized to employees via company policy such as this and may also be included in general or specific compliance trainings.

Amplifon will respond to an Employee, Contractor, or Board member's violation of the Compliance Program on a case-by-case basis, depending on the facts and circumstances of the violation. Disciplinary action may include, but is not limited to:

- Reeducation on Compliance Program guidelines.
- A verbal warning.
- A written warning to the Employee's or Contractor's file.
- Suspension; or
- Termination of employment.

Amplifon reserves the right to bypass any of the steps listed above, including moving to immediate termination of an Employee, Contractor, or Board member for violation of Compliance Program standards.

Amplifon will retain records of discipline associated with Compliance Program violations for a period of per the Document Retention Schedule Procedure.

6. Monitoring, Auditing, and Identification of Compliance Risks

Amplifon has established and implemented systems for routine monitoring, auditing, and identification of areas with potential risk for noncompliance. Annually, Amplifon will develop and implement a work plan that identifies and addresses potential areas of noncompliance with established compliance-program standards, as well as risks and vulnerabilities associated with its operations. The annual work-plan can be revised at any time to reflect changes to Amplifon's risk profile. The Compliance Officer will work with business units to identify appropriate areas for monitoring based on possible risks of non-compliance.

Amplifon's Audit function is carried out by Amplifon SpA, with engagement from the compliance department. Employee(s) or Contractor(s) dedicated to the Audit function will be responsible for auditing Departments to ensure compliance with relevant laws and regulations. Staff from other Departments may assist in Audit activities provided the assistance is compatible with the independence of the Audit function.

Amplifon will cooperate with any request for an external audit by a government regulator (or by their designee), or by an existing or potential partner (AHC contracted health plan, etc.). Amplifon will produce requested documentation in a timely manner as indicated by the auditor.

7. Procedures & System for Prompt Response to Compliance Issues including Concerns of Fraud, Waste, or Abuse (FWA)

Amplifon has established procedures and a system for promptly responding to compliance issues as they are raised; investigating potential compliance problems as identified during self-evaluations and audits; correcting such problems promptly and thoroughly to reduce the potential for recurrence; and ensuring ongoing compliance with laws, regulations, and Amplifon's compliance program.

The Compliance Officer is responsible for monitoring adherence to all aspects of the Amplifon Compliance Program. If Amplifon learns of a compliance incident or issue, an inquiry will be initiated as quickly as possible. If, after a preliminary investigation, the Compliance Officer determines that Amplifon does not have the time and/or resources to investigate the issue accordingly, they will refer the matter to the appropriate regulatory body, or other affected parties (including impacted Amplifon Hearing Health Care plans/customers) within 30 days of the date the potential FWA is reported, or in the specified plan timeframe, so that the potential FWA activity does not continue.

Corrective Actions

Amplifon will take appropriate corrective action(s) in response to potential or confirmed instances of noncompliance with the established Compliance Program requirements. This includes designing corrective actions tailored to correct the underlying problem that resulted in program violations, as well as to prevent future noncompliance. To that end, Amplifon will:

- Conduct a root-cause analysis to determine what caused or allowed the issue or deficiency to occur.
- Tailor corrective actions to address the facts and circumstances of the noncompliance.
- Set timeframes for specific achievements.
- Document the corrective action, including the ramifications if the corrective action is not successfully implemented.
- Enforce corrective action through disciplinary measures; and

- Maintain thorough documentation of all identified deficiencies and corrective actions taken.

Procedure(s)

Please review Amplifon Intranet for related compliance procedures.

Related Policy and/or Procedure Documents

CP-001.002 Compliance Reporting Mechanism Procedures

CP-004.001 Document Retention Schedule Procedure

References

42 CFR § 422.503 - General provisions.

United States Sentencing Commission - §8B2.1. Effective Compliance and Ethics Program

Version Number	Date of Review	Who Reviewed	Brief Summary of Revisions (If None, Write None)
2022.A	May 3, 2022	Andrea Johnson	Converted document to the new template including the new versioning section.
2022.B	November 11, 2022	Andrea Johnson	Added more detailed language to the fraud, waste, and abuse section. Updated language throughout related to references to Medicare.
2023.A	February 7, 2023	Andrea Johnson	Reviewed and added a section about requiring confidentiality agreements during onboarding.
2023.B	March 10, 2023	Andrea Johnson	Removed references to volunteers, Amplifon USA does not have volunteers. Only Miracle-Ear Foundation has volunteers and they are handled differently than employees and contractors.