POLICY DEVELOPMENT AND MANAGEMENT PROCEDURE

POLICY NUMBER:	CP-001.001	CREATED:	SEPTEMBER 2018
DEPARTMENT:	COMPLIANCE	EFFECTIVE DATE:	OCTOBER 2021
RESPONSIBLE PARTY:	COMPLIANCE MANAGER	LAST REVISED:	OCTOBER 2020
APPROVAL AUTHORITY:	COMPLIANCE OFFICER	NEXT REVIEW DATE:	OCTOBER 2021

Purpose

The purpose of this procedure is to establish clear standards for the development and implementation of policies and procedures in a manner that ensures compliance with all relevant laws and regulations.

Scope

This Policy applies to all policies, procedures, and desktop instructions throughout Amplifon.

Key Terms

Please Refer to Amplifon Compliance Policy Definitions.

Procedures

1. The Compliance Officer is the Responsible Party for development, and subsequent revision, of new policies and procedures related to the structure and operation of the Compliance Program.

2. The Compliance Officer and the Compliance Committee are responsible for ensuring that policies and procedures related to the structure and operation of the Compliance Program have been developed, implemented, and are reviewed annually.

3. All compliance program-related policies will be submitted for approval to the Compliance Committee as the Approval Authority. These policies and must describe the compliance issues in question, as well as a description of how the Policy will address the compliance issues. When requested, the Compliance Committee will receive a presentation of the Policy for approval.

4. Policies & procedures are to be reviewed annually and evaluated for revision and updating.

5. Policies and procedures related to operational compliance will be developed and revised at the direction of Senior Management, who will appoint a Responsible Party appropriate for the policy in question.

6. Each Responsible Party is charged with the following:
   a. Working with Regulatory Affairs, Legal and Compliance to identify relevant laws & regulations related to their business units. Developing policies and procedures designed to ensure operations are conducted in compliance with current laws, regulations, and organizational policies.
   b. Ensuring approved policies are posted on the Intranet.
   c. Ensuring the appropriate distribution & training to those who are responsible for acting in accordance with Policies and Procedures, including documentation of that training.

d. In conjunction with the compliance department, determining whether existing policies and procedures address identified risk issues.

e. Ensuring that compliance-related policies and procedures related to their areas of responsibility are current and up to date.

f. Spearheading the annual review and revision process (this includes Policies and the related Procedures and Desktop Instructions), and ensuring it takes place in a timely and an organized manner.

g. Report to Senior Management on the status of Policy updates as requested.

h. Maintaining a Departmental history file of non-current Policies for reference.

7. The following general format should be used for all policies and procedures:

Heading. The heading includes the (a) Policy Title (top of the document), (b) Approval Authority, (c) Policy Number, (d) Department, (e) Responsible Party, (f) Date Created, (g) Effective Date, (h) Date Last Revised, and (i) Scheduled Revision Date.

a. Policy Naming Convention. All Amplifon Policies, Procedures, and Desktop Instructions will be named according to the guidelines in Paragraph 10, below.

b. Purpose. Outlines the reason for or scope of the policy/procedure.

c. Scope. Defines the individuals and/or Departments covered by the policy.

d. Key Terms. Provides definitions for important terms used in the policy or links to a definitions document.

e. Policy. Reflects the basic objectives of the organization and is a description of the general principles or courses of action.

f. Procedure. Provides detailed procedural requirements and methods.

g. Regulations Reference. Describes specific details of regulations or other authority that are reflected in the policy. All new policies and revised policies should note relevant regulatory/accreditation requirements that affect the policy's content. (If there are no requirements, indicate "None.")

h. Related Policy and Compliance Documents. Provides references to other relevant Amplifon Policies, procedures and/or desktop instructions.

8. All Policies remain in effect until they are revised or archived. All historical versions of policies (rescinded and revised) will be maintained to provide the ability to reference a version of a policy in effect at a specified point in time.

9. Any substantive revision made to an approved policy/procedure must go through the full review and approval process.

10. All compliance-related policy records will be managed and maintained by the Policy Administrator in a systematic and logical manner and consistent with applicable law and regulation.

a. The Policy Administrator will:

   i. Manage the process of archiving rescinded policies and procedures

   ii. Maintain a master list of Policy revision dates containing the following fields:

      1. Function
      2. Policy name
      3. Policy number
      4. Responsible Party
      5. Date Policy was last revised
      6. Next scheduled revision date.

11. Current Policies will be distributed and stored in the following manner:
   a. Policies will be stored on the Amplifon intranet under "Policies and Procedures
   b. A Policy's location will depend upon how widely the Policy needs to be distributed and
   c. Any Policy posted for any audience will be in PDF form.

12. Policies will be named according to the following conventions:
   a. Policies will be given names that correspond to the function responsible for the policy. Functions (FN) are:
      i. Compliance Program (CP)
      ii. General Administration (GA)
      iii. Procurement & Vendor Management (PVM)
      iv. Marketing (MKG)
      v. Information Technology (IT)
      vi. Finance (FIN)
      vii. Human Resources (HR)
      viii. Amplifon Hearing Health Care (AHHC)
      ix. Amplifon Canada (CAN)
      x. Miracle-Ear Foundation (FDN)
   b. Within each Function (FN), policies will be given a unique number (PN). Policies must be numbered consecutively. Departments must work with Policy Administrator to ensure consecutive numbering.
   c. For Procedures (PR) and Desktop Instructions (DI), there will be an additional number after the Policy number with which it is associated. These numbers, too, must be consecutive with any other PR or DI for the relevant policy.

13. The following is the naming convention for all policies:
   For a Policy: YEAR FN-PN POLICY NAME
   For a Procedure: YEAR FN-PN.PR PROCEDURE NAME
   For Desktop Instructions: YEAR FN-PN.DI DESKTOP INSTRUCTION NAME

If a Policy is reviewed and no changes are made during the annual review process, the YEAR portion of the title still needs to be updated to reflect the current year.

Related Policy and Compliance Documents

2020 CP-001 Amplifon Compliance Program Policy

References

Medicare Managed Care Manual Chapter 21: Compliance Program Guidelines