



UnitedHealthcare®

EDO Compliance Toolkit (Guide)

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Introduction

Expectations of UnitedHealthcare Medicare and Retirement

Honesty and integrity are core values to UnitedHealthcare Medicare and Retirement. UnitedHealthcare expects its business partners including the External Distribution Organizations (collectively, “EDO”, “you”, or “your”) to incorporate these values and to act with the highest degree of integrity and ethical standards. External Distribution Organizations, for the purpose of this document, includes all national marketing alliance organizations, Telesales vendors and eAlliance partners. As a Plan Sponsor contracted with the Centers of Medicare and Medicaid Services (“CMS”), UnitedHealthcare is required to maintain effective oversight of its EDOs to ensure their full compliance with CMS regulations. In an effort to enhance our oversight activities, we are happy to provide you with this EDO Toolkit, which contains the UnitedHealthcare EDO Compliance Plan.

A Compliance Program begins with a Code of Conduct. UnitedHealth Group distributes its Code of Conduct and expects EDOs to adopt this Code. EDOs may create their own Codes of Conduct; however, these must meet the standards outlined in the CMS Chapter 9/21 Compliance Program guidelines of the Medicare Managed Care Manual.

We also require that you establish a Compliance Program which incorporates the seven

(7) elements of an effective Compliance Program, as mandated by CMS, and as described in the CMS Chapter 9/21 Compliance Program guidelines of the Medicare Managed Care Manual. The seven elements are included herein as **Appendix A**.

As part of an effective compliance program, the Centers for Medicare and Medicaid Services (CMS) and other federal and state regulators require that UnitedHealth Group and its affiliate organizations (collectively, our organization) communicate and monitor specific compliance and fraud, waste and abuse (FWA) requirements to our employees and delegated entities (delegates) – including first tier, downstream, and related entities (FDRs). In the event of a CMS, federal or state audit, our organization must demonstrate that we evaluate our delegates’ compliance with program requirements, including effective monitoring and oversight of such delegates. As a Delegated Entity of UnitedHealth Group, certain requirements must be addressed within your organization. These requirements are outlined in further detail later in this document.

Our organization uses the terms:

delegates; delegated entities; vendor; first-tier, downstream entity and related entity (FDR); subcontractor; and, occasionally, others interchangeably to name the parties with whom we contract with to support administration of benefits, access to care and other services performed on our behalf.

EDO Compliance Program Elements

As mentioned in the Introduction, a core set of documentation is the cornerstone to a successful compliance program. As a valuable business partner, we want to help you create and maintain a successful Compliance Program and have provided the following documentation to assist you.

The foundation of your compliance program will be documented in your Compliance Program Charter. Your Charter is intended to outline, and be evidence of, an EDO's Compliance Program. A template EDO Compliance Program Charter is included in **Appendix B**.

The principal purpose of the EDO Compliance Program is to promote and facilitate corporate governance of operations and services rendered in accordance with established laws, regulatory requirements and UnitedHealthcare policies. The EDO Compliance Program ensures the business operations of our EDOs reflect the values, integrity and commitment to compliance that UnitedHealthcare shares with its members, constituents and stakeholders.

Your compliance program will include the seven key elements of an effective Compliance Program (Appendix A) which will foster a culture that promotes prevention and detection of conduct that does not conform to the laws, regulations and company policies associated with government-funded healthcare programs. The 7 elements include:

1. Written policies and procedures
2. Compliance Officer and Compliance Committee
3. Effective training and education
4. Effective lines of communication (including anonymous reporting function)
5. Internal monitoring and auditing
6. Disciplinary enforcement
7. Mechanisms for responding to and reporting detected problems

Policies and Procedures

The EDO Compliance Program should develop and distribute written compliance standards, procedures and practices to guide the EDO and its employees in their UnitedHealthcare-related activity on a day-to-day basis. These begin with the EDO Code of Conduct, detailing the fundamental principles, values and framework for action within the Organization; general policies and procedures to provide guidance for any state or federal specific regulations associated with the day-to-day business. These should be easily understood, posted in public spaces within the office area and distributed to all affected employees including all contracted broker/agents within the EDO's downline. These policies should also be reviewed and revised as necessary and on an annual basis.

What does this mean to you?

UnitedHealthcare believes that the core Policies and Procedures needed to establish a robust Compliance Program should include, at a minimum, the following topics:

1. **Privacy and Security.** A policy on privacy and security should address access to, disclosure and use of beneficiary personal information; encryption and decryption of email transmissions; secure disposal of beneficiary personal information; workstation use and security; breach of security and required reporting and resolution activities.
2. **Policy on Policies.** A policy on policies should address such topics as policy naming conventions; policy formatting; at least an annual policy review and revision schedule; policy ownership determination and policy approval processes.
3. **Agent Oversight.** A policy on agent oversight should include details of who will conduct agent oversight activities; what aspects of agent activity will be monitored; how that oversight will be conducted and the frequency with which it will be conducted.
4. **Training and Education.** A policy on training and education should address such topics as frequency, methods and testing requirements of all training and education requirements and offerings as well as topics to be covered.
5. **Corrective and Disciplinary Action.** A policy on corrective and disciplinary action should address what actions will prompt corrective or disciplinary action, progressive disciplinary levels and who will administer such discipline. This policy should define the grounds for termination.

A sample Policy and Procedure (P&P) template has been included for you to use in drafting your applicable Policies and Procedures (**Appendix C**). This template document outlines the basic expectations of the policy and procedure structure and information. Policies and procedures should contain the following elements:

1. **Policy Applicability** – stakeholders, products and functional and accountable owners related to the P&P. Owners in this context refers to the individual(s) or business unit/department responsible for implementing and managing the processes defined in the policy and procedure document.
2. **Policy Statement** – outlines specific responsibility to the administration and governance of the requirements stated in the policy.

3. **Policy Purpose/Scope** – the intent of the P&P – who it applies to, what process it is designed to oversee/monitor, etc.
4. **Policy Definitions** – Key terms and descriptions, whether they relate to processes or department names
5. **Policy Provisions and Exhibits** (Procedure – see template Exhibit xx
6. **References** – list any references, links, and refer to related policies where applicable.
7. **Document History** – record of changes and updates, including version number, date and description of changes made or approval, etc.

Delegated Entity (FDR) Regulatory Compliance Program Requirements for Medicare

Background

The Centers for Medicare & Medicaid Services (CMS) requires that we communicate general compliance program information and requirements, as well as provide training and education and monitor specific Compliance requirements to our employees and delegates – including first tier, downstream, and related entities.

General information, definitions and links are available on our [Compliance Program - UnitedHealth Group](#) website. The site also links to specific compliance guidance and information on the attestation process for Medicare, Medicaid and other government programs. You can also view a sample attestation form that has more information about each requirement

What does this mean for your organization?

Review the following compliance requirements and ensure you and any applicable affiliate organizations* can meet all the requirements. If you are unable to meet any of these requirements please contact us to discuss.

Employees are defined as hired staff, management and temporary workers for your company or subcontractors that have involvement in or responsibility for a delegated core function in the administration or delivery of Medicare Advantage Part C, Part D, or Medicaid health plan benefits and have access to personal health information/personally identifiable information (PHI/PII).

1. Code of Conduct Distribution:

Delegate must distribute their own written policies, procedures or standards of conduct **or** the UnitedHealth Group Code of Conduct to employees who support the administration or delivery of program benefits or services.

- Must be distributed within 90 days of hire and annually thereafter.
- Delegate must retain proof of distribution for each employee.

Resource: [Ethics & Compliance - UnitedHealth Group](#)

2. FWA and General Compliance Training

- Effective January 1, 2019, CMS no longer requires FDR's to use the CMS modules for FWA and General Compliance Training or provide evidence of training within specific time periods. It is important to note that all FDR's are still required to know, understand and follow all FWA and General Compliance regulations and requirements.
- We all have the obligation to combat FWA and should be aware of how to identify and report FWA and non-compliance - if you need assistance in training, or more info on FWA and general compliance guidance, please check out the information provided on our website.

3. OIG/GSA/State Exclusion Checks:

CMS and other federal and state regulators prohibit you from hiring, employing or making payments to any person or business excluded or debarred from federal or state health care programs. You must perform checks against the Office of Inspector General (OIG) and General Services Administration (GSA) federal exclusion lists prior to hire and monthly thereafter.

UnitedHealthcare FDRs serving UnitedHealthcare Community Plan programs must also review state level exclusion lists as applicable to the services the FDR is contracted to perform.

Resources: [General Compliance - UnitedHealth Group](#) under the drop down for "Exclusion Checks"

- The exclusion review requirement is listed under Title 42 Public Health CFR §1001.1901(b). The state exclusion list requirement is listed under Title 42 Public Health CFR § 1002.2; Authority also includes applicable state law and state Medicaid contracts, which control all services performed for UnitedHealthcare Community Plan in any given state.
- Health and Human Services Office of Inspector General
- General Services Admission (GSA)
- State Medicaid Exclusions

4. Notification of All Offshoring:

For CMS, Medicare Advantage Plans must submit off-shore contractor information and attestations within 30 calendar days of signing an off-shore contract.

For Medicaid, health plans are prohibited from making payments to financial institutions or entities located outside the United States for services furnished by a provider, contracted or otherwise, to a Medicaid managed care member.

Failure to notify and obtain express written approval is in violation of regulatory and contractual requirements as defined by applicable laws, regulations and policies.

Reporting to Medicare: To report Medicare offshoring, email medicare_offshoring@uhc.com

Reporting to Medicaid: To report Medicaid offshoring, contact your UnitedHealthcare Community Plan representative.

5. Document Retention: You must keep all CMS documentation a minimum of 10 years.

Maintain records for 10 years that show that you have met these FDR requirements. You may be called upon by us or CMS to provide documentation upon request. Examples of documentation include: (1) communication of Standards of Conduct in an email, website portal or contract; (2) method of OIG/GSA and state (if applicable) exclusion checks and a copy of a sanction check report for each non-agent/non-licensed employee/contractor; and (3) policy(s) and procedure(s) that describe the process(es) you use to meet the preceding requirements.

6. Monitoring and/or Auditing of Subcontracted Delegates/Vendors:

Downstream entities or subcontractors that support the delivery or administration of program benefits or services are held to the same Compliance Program requirements.

A delegated entity and their downstream subcontracted delegates that handle PHI/PII must meet specific Compliance requirements when engaged to perform administrative or health care services for Medicare Part C & Part D and Medicaid health plans/members. They must ensure compliance with any state- or program- specific regulatory requirements for Medicaid; and check against any state- specific regulatory appendix attachment or regulatory requirements articulated in the contract.

Reporting Potential Fraud, Waste and Abuse or Compliance Concerns to UnitedHealth Group

If you suspect misconduct or if you identify an excluded individual or entity employed or contracted by your organization, report it to us immediately so we may investigate and respond appropriately. You can report this either to your UnitedHealthcare Contract Manager, business contact, or by using one of the methods below:

- To report FWA concerns: report online at uhc.com/fraud or by calling 844-359-7736.
- To report other Compliance & Ethics Concerns: you may email EthicsOffice@uhg.com, report online at UHGhelpcenter.ethicspoint.com, or by calling 800-455-4521.

Reports to the HelpCenter can be made anonymously, where permitted by law. UHG prohibits retaliation and intimidation for reports made in good faith.

General Information & Contacts

General information, definitions and links are available on our [UnitedHealth Group Delegated Entity Compliance Program](#) website. The site also links to specific compliance guidance and information on the attestation process for Medicare, Medicaid and other government programs.

Important telephone numbers and contact information

General compliance questions: compliance_questions@uhc.com

FDR regulatory requirement questions: decompliance@uhc.com

To report a privacy/security incident or breach, please contact The Ethics Office: Telephone: [800-455-4521](tel:800-455-4521) or by email: Ethics-Integrity_Office@uhc.com

Definitions

Abuse - Includes actions that may, directly or indirectly, result in: unnecessary costs to the Medicare Program, improper payment, payment for services that fail to meet professionally recognized standards of care, or services that are medically unnecessary. Abuse involves payment for items or services when there is no legal entitlement to that payment and the provider has not knowingly and/or intentionally misrepresented facts to obtain payment. Abuse cannot be differentiated categorically from fraud, because the distinction between “fraud” and “abuse” depends on specific facts and circumstances, intent and prior knowledge, and available evidence, among other factors.

Audit - A formal review of compliance with a particular set of standards (e.g., policies and procedures, laws and regulations) used as base measures.

Breach -The acquisition, access, use or disclosure of protected health information in a manner not permitted under the HIPAA Privacy Rule which compromises the security or privacy of the protected health information.

Delegated Entity - Delegated Entity definitions are outlined for the Medicare and program below.

Medicare Program Specific First Tier, Downstream and Related Entity (FDR) Delegated Entity Definitions – as specified in 42 CFR § 422.2; 42 CFR § 423.4 and 42 C.F.R. §, 423.501

- First Tier Entity – First tier entity means any party that enters into a written arrangement, acceptable to CMS, with an MA organization or Part D plan sponsor or applicant to provide administrative services or health care services for a Medicare eligible individual under the MA program or Part D.
- Downstream Entity – Downstream entity means any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the MA or Part D benefit, below the level of the arrangement between an MA organization or 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.
- Related Entity – Related entity means any entity that is related to the MA organization or Part D plan sponsor by common ownership or control and (1) Performs some of the MA organization’s or Part D plan sponsor’s management functions under contract or delegation; (2) Furnishes services to Medicare enrollees under an oral or written agreement; or (3) Leases real property or sells materials to the MA organization or Part D plan sponsor at a cost of more than \$2,500 during a contract period.

Downstream Entity- 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).

Employee(s) - Refers to those persons employed by the sponsor or a First Tier, Downstream or Related Entity (FDR) who provide health or administrative services for an enrollee. This includes hired staff, management and temporary workers for your company or subcontractors that have involvement in or responsibility for a delegated core function in the administration or delivery of Medicare Advantage Part C or Part D, or Community & State health plan benefits and have access to PHI/PII

EDO –External Distribution Organization

EDC –External Distribution Channel

FDR - First Tier, Downstream or Related Entity.

First Tier Entity- 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).

Fraud- Knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any health care benefit program or to obtain (by means of false or fraudulent pretenses, representations, or promises) any of the money or property owned by, or under the custody or control of, any health care benefit program. 18 U.S.C. § 1347.

FWA - Fraud, Waste and Abuse.

GSA - General Services Administration. GSA System for Award Management (SAM)

Medicare- The health insurance program for the following:

- People 65 or older,
- People under 65 with certain disabilities, or
- People of any age with End-Stage Renal Disease (ESRD) (permanent kidney failure requiring dialysis or a kidney transplant).

Monitoring/Detection- Regular reviews performed as part of normal operations to confirm ongoing compliance and to ensure that corrective actions are undertaken and effective.

OIG - Office of the Inspector General within DHHS. The Inspector General is responsible for audits, evaluations, investigations, and law enforcement efforts relating to DHHS programs and operations, including the Medicare program.

Protected Health Information (PHI) - Any information about a potential or actual member that demonstrates the individual has or is seeking health insurance from UnitedHealth Group. All member/customer information, including demographics, should be considered protected and confidential.

Rapid Disenrollment - When a beneficiary disenrolls from a plan within the first three months of enrollment

Risk Assessment/Identification- Determining the likelihood that a specific negative event will occur

Waste - The overutilization of services, or other practices that, directly or indirectly, result in unnecessary costs to the Medicare program. Waste is generally not considered to be caused by criminally negligent actions but rather the misuse of resources.

Appendix A: 7 Elements of an Effective Compliance Program

1. Policies and Procedures, Including a Statement of Corporate Philosophy and Codes of Conduct. The program should develop and distribute written compliance standards, procedures and practices to guide the EDO and its employees on a day- to-day basis. These should include a Code of Conduct detailing the fundamental principles, values and framework for action within the organization; general corporate policies and procedures and guidance for any state or federal specific regulations associated with the day-to-day business. These should be easily understood by, and posted and distributed to, all affected employees including all contracted broker/agents and their downlines.

The EDO Compliance Program must maintain a central repository of all processes and procedures developed in support of the Compliance Program. Procedures and processes must be periodically reviewed to ensure accuracy with current business operations and regulatory and company requirements.

2. Designation of a Compliance Officer and Compliance Committee. An effective compliance program must have a compliance lead and often a compliance committee who are responsible for developing, operating and monitoring the compliance program. They must report directly to the EDO Principal/Owner, its governing body, and CEO, periodically and on an as-needed basis. The compliance officer must oversee the program, including making revisions as the EDOs needs change, coordinating and participating in training and education for employees, independently investigating compliance matters and ensuring that any necessary corrective action is taken.

3. Effective Training and Education. A necessary component of an effective compliance program is the proper and periodic education and training of all EDO personnel and contracted agents at all levels. EDO Compliance organizations must administer training specific to requirements to ensure understanding of applicable laws, regulations and policies. This training should be in addition to any mandatory annual certification training/testing requirements.

4. Developing Effective Lines of Communication. The compliance officer must create and maintain effective lines of communication with all employees, contractors and UnitedHealthcare. This may include a process, such as a hotline or other reporting system, to encourage questions and complaints and procedures to protect the confidentiality or reports and anonymity of the complainants and to protect employees against retaliation.

5. Internal Auditing and Monitoring. To demonstrate a compliance program's effectiveness, the EDO should monitor its implementation of the compliance program through a process of ongoing evaluation. Information gathered from monitoring efforts may result in the correction and/or modification of EDO internal processes; re-coaching and re-training efforts of employees and/or contractors or; disciplinary action taken by the EDO and/or UnitedHealthcare. EDO Compliance organizations must immediately notify UnitedHealthcare of any egregious compliance failure.

6. Disciplinary Enforcement. An effective compliance program should set out the consequences for employees or contractors who violate the EDOs standards of conduct, policies and procedures, and Federal and State laws. It should describe the procedures for handling such disciplinary problems. Appropriate disciplinary actions should occur as a result of compliance issues.

7. Mechanisms for responding to and reporting detected problems. All reports and/or indications of suspected noncompliance must result in an immediate investigation to determine whether there has been a violation of law or other requirements and, if so, decisive steps to correct the problem. EDO Compliance organizations must immediately notify UnitedHealthcare Compliance of any egregious compliance violation(s).

Appendix B: Compliance Program Charter Template

EDO Compliance Program Charter

This document is intended to outline and be evidence of, an EDO's Compliance Program. Included for your reference below is an outline that can be used as a template EDO Compliance Program Charter by your organization.

Introduction: [state the purpose of your compliance program; mission etc..]

Example: The principle purpose of the EDO Compliance Program is to promote and facilitate corporate governance of operations and services rendered in accordance with established laws, regulatory requirements and UnitedHealthcare Policies. The EDO Compliance Program ensures the business operations of our EDO's reflect the values, integrity and commitment to compliance that UnitedHealthcare shares with its members, constituents and stakeholders.

Responsibilities and Obligations: [outline the high level responsibilities of the compliance program. This should include the 7 elements of an effective compliance program and provide a high level plan for incorporating these elements within your organization.]

Example: The EDO Compliance Program is guided by the principles contained within UnitedHealthcare's Corporate Responsibility and Compliance Program. EDO Compliance Organizations will include the 7 key elements of an effective compliance program which will foster a culture that promotes prevention and detection of conduct that does not conform to the laws, regulations and company policies associated with government-funded healthcare programs. The 7 elements include:

- 1. Written policies and procedures** – [example: The policies and procedures of [your organization] should serve as a guide for its employees, contracted agents and business partners in regards to compliance standards and the procedures and practices relating to compliance.]
- 2. Compliance Officer and Compliance Committee** [example: An effective compliance program must have a compliance officer to oversee the entire program. The compliance officer's responsibilities include developing, operating and monitoring the compliance program; along with reporting to management on a periodic and as needed basis. The compliance officer will also be responsible for coordinating and participating in the training of all employees, independently investigating compliance matters, if applicable, and ensuring that any necessary corrective action is taken.
- 3. Effective training and education** [example: A necessary component of every compliance program is proper and periodic training. This training and education should help all individuals who do work on behalf of the organization understand the laws, regulations and policies applicable to their day to day business activities. All employees will be trained to ensure they've gained the necessary knowledge of all laws, regulations, and best practices of a successful Compliance Program
- 4. Effective lines of communication** (including anonymous reporting function): [example: Effective lines of communication are critical to the success of any business operation, and a compliance program is no different. The compliance officer must create and maintain effective lines of communication. The success of the program is reliant on all employees and staff having an effective way to ask questions and report concerns or violations, without fear of reprisal or retaliation, when the need arises.
- 5. Internal monitoring and auditing** [example: The implementation of ongoing evaluation and monitoring processes of our business to ensure its effectiveness. [Our organization] will utilize multiple avenues for

internal monitoring and auditing purposes. Processes may be implemented to monitor day-to-day operations and practices to ensure our organization is remaining compliant. Information gathered from the evaluation process will be used to prevent, detect and correct compliance risks and deficiencies identified.]

6. Disciplinary enforcement – [Example: Depending on the severity of violations, re-training and disciplinary actions up to and including termination may be taken if the monitoring and auditing process uncovers any egregious compliance errors. The disciplinary action will be fair, equitable and consistent, and the severity of the infraction will determine the steps taken.]

7. Mechanisms for responding to and reporting detected problems [Example: All reports and/or indications of suspected noncompliance will result in an investigation to determine whether there has been a violation of law or other requirements; and, if so, make sure all affected parties are notified of the breach, and do everything possible to correct/minimize the severity of the violation]

Structure and Membership of EDO Compliance Organizations:

The structure of the EDO Compliance Program will vary in accordance with the size and complexity of the EDO's operations. The structure and membership of the compliance program must be designed in such a way to ensure the duties and responsibilities identified above are successfully performed, the Compliance Program will be comprised of key management staff members for oversight of agency efforts in meeting the UnitedHealthcare contractual and business expectations.

Outline the structure of your compliance program. Who (by title /position is recommended rather than named individuals) will be part of your compliance committee and what their role is within the committee. You should include members from key areas within your business operation to ensure effective communication and oversight of all areas.

Knowledge of Regulations and UnitedHealthcare Company Policy: [Provide information on how you will maintain knowledge of and compliance with the regulatory requirements, company policies and general compliance requirements pertaining to your business]

Example: The EDO Compliance Program will work with UnitedHealthcare to establish and maintain an inventory of applicable UnitedHealthcare policy and procedure documents and regulatory guidance documents applicable to their marketing and sales activities. Additionally, broader, more general compliance requirements pertaining to, but not limited to, Information Security, Records Management, Privacy and Security Awareness and Fraud, Waste and Abuse, should be created and maintained by the EDO Compliance Program.

Oversight of EDO Compliance Program: [use this section to outline high level process/programs that will allow you to have oversight of your organization and ensure ongoing compliance]

Example: Regular reviews and inquiries of EDO Compliance operations and performance may be conducted by UnitedHealthcare for various purposes including monitoring and audit functions. Compliance standards and metrics have been implemented to assess the effectiveness of the EDO Compliance Program and are measured via the Dashboard reports, distributed to each EDO on a regular basis and described in greater detail herein.

Policies and Procedures [outline general policies and procedures that the organization has in place to ensure compliance with all requirements. These should include the core policies outlined in the toolkit. Additionally, outline the mechanisms in place to review and update your policies at least annually, or when changes occur. This should include the review and approval process and timing etc.]

Appendix C: P&P Sample Template

<p>Policy and Procedure Business Owner: Organization to which P&P Belongs</p>	<p>Effective Date: Date P&P goes into effect XX/XX/10 List revision dates</p>
<p>Policy Title: Title of P&P</p>	<p>Document Number: tracking number for P&P</p>

I. POLICY APPLICABILITY (stakeholders, products and functional owners related to P&P)

STAKEHOLDERS	PRODUCTS	FUNCTIONAL OWNERS
	List Products impacted here	

II. POLICY STATEMENT

A precise statement regarding the organizations responsibility pertaining to the governance and administration of requirements contained within the P&P.

III. POLICY PURPOSE (Scope)

The intent and scope of the P&P. A statement of the overall process of the P&P and to whom it applies (by organization, department). P&P must state specifically the sales & marketing channels it pertains to.

IV. POLICY DEFINITIONS

Refer to Definitions P&P: The text in this section will be the same for all P&Ps. It includes key terms and descriptions, whether they relate to department names or processes. Ensure that key definitions used in this P&P are included in a Master Definitions P&P. If key definitions are missing from the Master Definitions P&P, provide those definitions to the Policy and Procedure Manager.

V. POLICY PROVISIONS and EXHIBITS (Procedure)

Description of the procedures and processes needed to implement P&P. May include:

- Description of steps to be taken (inputs, outputs, hand-offs, end-to-end processes...etc.)
- Specific designation of ownership (what business unit or department is to perform certain activities)
- Specific CMS, regulatory and/or corporate requirements
- Timeframes for performance of procedure(s)
- Reporting system(s)
- Location(s) where procedure is to be performed (if applicable)
- Documentation and maintenance requirements (if any)

This section can be written in standard paragraph format or in outline format. If written in outline format use the following formatting convention:

- A.
- 1.
 - a.
 - i.

VI. RELATED DOCUMENTS, REFERENCE LINKS, RELATED POLICIES (Where Applicable)

References

List of reference documents/resources either mentioned within or consulted during development of P&P (other P&Ps...etc.). Provide link to reference item (if available). Do not attach reference item;

1. First reference
2. Second reference

Attachments

Supporting documents that are integral to the processes within the P&P (Guidance Documents, Process Flows...etc.). Not applicable to related P&Ps;

Insert first attachment if applicable

Insert second attachment if applicable

VI. DOCUMENT HISTORY

Chronological listing of all current and prior versions of the P&P. Including brief description of key edits to the version.

Approved xx/xx/xxxx	Revised xx/xx/xxxx/