UnitedHealthcare®

EDO Compliance Toolkit (Guide)

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United Healthcare®

Introduction

Expectations of UnitedHealthcare Medicare and Retirement

UnitedHealthcare Medicare and Retirement values honesty and integrity. We expect our business partners, including External Distribution Organizations (EDOs), to uphold these standards. EDOs include national marketing alliances, Telesales vendors, and eAlliance partners. As a Plan Sponsor contracted with the Centers for Medicare and Medicaid Services (CMS), UnitedHealthcare is required to oversee its EDOs to ensure compliance with CMS regulations. To improve oversight, we provide this EDO Toolkit, which includes the UnitedHealthcare EDO Compliance Plan

Compliance Program

A Compliance Program starts with a Code of Conduct. UnitedHealth Group provides its Code of Conduct and expects EDOs to follow it. EDOs can create their own Codes of Conduct, but they must meet the standards in the CMS Compliance Program guidelines found in the Medicare Managed Care Manual, Chapter 21 and Prescription Drug Benefit Manual, Chapter 9.

We also require that you establish a Compliance Program that includes the seven elements required by CMS, as outlined in the CMS Compliance Program guidelines. These elements are listed in Appendix A.

Communication and Monitoring

UnitedHealth Group and its affiliates must communicate and monitor compliance and fraud, waste, and abuse (FWA) requirements to employees and delegated entities (delegates), including first tier, downstream, and related entities (FDRs). During a CMS, federal, or state audit, UnitedHealth Group must show that it evaluates its delegates' compliance with program requirements. As a Delegated Entity, your organization must address certain requirements, which are detailed later in the document.

Terminology

Our organization uses the terms: delegates; delegated entities; vendor; first-tier, downstream entity and related entity (FDR); subcontractor; and, occasionally, others interchangeably 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

A successful compliance program relies on a core set of documentation. As a valuable business partner, we want to help you create and maintain a successful Compliance Program. The following documentation is provided to assist you:

- **Compliance Program Charter:** This foundational document outlines and serves as evidence of an EDO's Compliance Program. A template is included in **Appendix B.**

  The EDO Compliance Program promotes and facilitates corporate governance of operations and services in accordance with laws, regulatory requirements, and UnitedHealthcare policies. It ensures that EDO business operations reflect the values, integrity, and commitment to compliance shared by UnitedHealthcare with its members, constituents, and stakeholders.

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

  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 daily activities related to UnitedHealthcare. These standards start with the EDO Code of Conduct, which outlines fundamental principles, values, and actions. General policies and procedures should provide guidance for any state or federal regulations associated with daily business. These should be easy to understand, posted in public spaces within the office, and distributed to all affected employees, including contracted brokers/agents within the EDO's downline. Policies should be reviewed and revised as necessary and annually.

Core Policies and Procedures

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**: 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**: Address topics such as policy naming conventions, formatting, annual review and revision schedule, policy ownership determination, and approval processes.

3. **Agent Oversight**: Include details of who will conduct agent oversight activities, what aspects of agent activity will be monitored, how oversight will be conducted, and the frequency of oversight.

4. **Training and Education**: Address frequency, methods, testing requirements, and topics to be covered in training and education.

5. **Corrective and Disciplinary Action**: Define actions that will prompt corrective or disciplinary action, progressive disciplinary levels, and who will administer discipline. This policy should also define grounds for termination.

A sample Policy and Procedure (P&P) template is included in **Appendix C**. This template outlines the basic expectations for 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 refer to individuals or business units/departments responsible for implementing and managing the processes defined in the policy and procedure document.

2. **Policy Statement:** Outline specific responsibilities for 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:** Detailed procedures and processes needed to implement the P&P. This may be included as exhibits.

6. **References:** List any references, links, and related policies where applicable.

7. **Document History:** – Record changes and updates, including version number, date, and description of changes made or approval.

Delegated Entity (FDR) Regulatory Compliance Program Requirements for Medicare

Background

The Centers for Medicare & Medicaid Services (CMS) requires us to communicate general compliance program information and requirements, provide training and education, and monitor specific compliance requirements to our employees and delegates, including first tier, downstream, and related entities (FDRs). 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 with 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 involved in or responsible 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)

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: Compliance Program- UnitedHealth Group

FWA and General Compliance Training

Effective January 1, 2019, CMS no longer requires FDRs to use the CMS modules for FWA and General Compliance Training or provide evidence of training within specific time periods. However, all FDRs 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. For assistance in training or more information on FWA and general compliance guidance, please

check out the information provided on our website.

OIG/GSA/State Exclusion Checks:

CMS and other federal and state regulators prohibit 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

- Compliance Program- UnitedHealth Group under the drop down for “Exclusion Checks”
- Health and Human Services Office of Inspector General
- General Services Admission (GSA)
- State Medicaid Exclusions

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.

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.

Document Retention

You must keep all CMS documentation for a minimum of 10 years. Maintain records for 10 years that show you have met these FDR requirements. You may be called upon by us or CMS to provide documentation upon request. Examples of documentation include:

- Communication of Standards of Conduct in an email, website portal, or contract.
- 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.

- Policies and procedures that describe the processes you use to meet the preceding requirements.

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 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 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 or by email: Ethics-Integrity_Office@uhc.com

Definitions

Abuse - According to CMS, abuse involves provider practices that are inconsistent with sound fiscal, business, or medical practices, resulting in unnecessary costs to the Medicaid program or reimbursement for services that are not medically necessary or fail to meet professionally recognized standards for health care

Abuse includes actions that lead to:

- Unnecessary costs to Medicare.
- Improper payments.
- Payments for services that don't meet professional standards or are medically unnecessary.

Abuse happens when payments are made for items or services without legal entitlement, even if the provider didn't intentionally misrepresent facts to get paid. The difference between abuse and fraud depends on specific details, intent, and evidence.

Audit - a systematic review or examination of records, processes, and practices to ensure compliance with regulations and standards.

Breach – acquisition, access, use or disclosure of protected health information (PHI) 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 - Any party that enters into a written arrangement, acceptable to CMS, with an MA organization or applicant to provide administrative services or health care services for a Medicare eligible individual under the MA or Part D program.

- Downstream Entity – means any party that enters into an acceptable written arrangement below the level of the arrangement between an MA or PDP organization (or contract 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 – means any entity that is related to the MA or Part D organization by common ownership or control and (1) Performs some of the MA or Part D organization'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 or Part D organization at a cost of more than $2,500 during a contract period.

- Downstream Entity - any party that enters into an acceptable written arrangement below the level of the arrangement between an MA or Part D organization (or contract applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

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.

Fraud- Under **18 U.S.C. § 1347**, fraud is defined specifically in the context of health care. It involves knowingly and willfully executing, or attempting to execute, a scheme to:

- Defraud any health care benefit program.
- Obtain money or property from a health care benefit program through false or fraudulent pretenses, representations, or promises

Penalties for violating this statute can include fines and imprisonment for up to 10 years. If the fraud results in serious bodily injury, the imprisonment can extend to 20 years, and if it results in death, the penalty can be life imprisonment

FWA - Fraud, Waste and Abuse.

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

Medicare - a federal health insurance program in the United States primarily for people aged 65 and older, but it also covers certain younger individuals with disabilities and those with End-Stage Renal Disease (ESRD).

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 health status, provision of health care, or payment for health care that can be linked to an individual.

Rapid Disenrollment - a situation where a beneficiary changes their Medicare Advantage (MA) or Part D plan within the first three months of enrollment

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

Waste – the overuse or inappropriate use of services and resources, which directly or indirectly results in unnecessary costs to healthcare programs. Waste typically involves practices that are not criminal or intentional but still lead to inefficiencies and higher expenses.

Appendix A: 7 Elements of an Effective Compliance Program

1. Policies and Procedures, Statement of Corporate Philosophy and Code of Conduct: The program should create and share written guidelines to help the EDO and its employees with daily tasks. These guidelines should include:

- A Code of Conduct outlining the organization's principles and values, and framework for action.
- General corporate policies and procedures.
- Guidance for state or federal regulations related to daily business.

These documents should be easy to understand and accessible to all affected employees, including brokers/agents and their teams.

The EDO Compliance Program must keep a central record of all processes and procedures. These should be regularly reviewed to ensure they are up to date with current business operations and regulations.

2. Designation of a Compliance Officer and Compliance Committee: An effective compliance program needs a compliance lead and often a compliance committee. They develop, operate, and monitor the program, reporting directly to the EDO Principal/Owner, governing body, and CEO periodically and as needed.

The compliance officer manages the program, updates it as needed, coordinates and participates in employee training, independently investigates compliance issues, and ensures corrective actions are taken.

3. Effective Training and Education: An effective compliance program requires regular education and training for all EDO personnel and contracted agents. EDO Compliance organizations must provide training to ensure understanding of relevant laws, regulations, and policies. This training should be in addition to mandatory annual certification requirements.

4. Developing Effective Communication Channels: The compliance officer needs to establish and keep open communication with all employees, contractors, and UnitedHealthcare. This can involve setting up a hotline or other reporting system to handle questions and complaints. There should also be procedures to ensure confidentiality and anonymity for those who report issues, and to protect employees from retaliation.

5. Internal Auditing and Monitoring: The EDO should regularly check how well the compliance program is working. This ongoing evaluation can lead to changes in internal processes, retraining employees or contractors, or taking disciplinary actions. If there is a serious compliance issue, the EDO must inform UnitedHealthcare immediately.

6. Disciplinary Enforcement: A good compliance program should explain what happens if employees or contractors break the rules or laws. It should outline how to deal with these issues and ensure that suitable disciplinary actions are taken.

7. Responding to and reporting problems: Any signs or reports of noncompliance must be investigated immediately to check for violations of laws or requirements.

- If a violation is found, prompt action must be taken to fix the issue.
- EDO Compliance organizations must inform UnitedHealthcare Compliance right away if there are any serious compliance violations.

Appendix B: Compliance Program Charter Template

EDO Compliance Program Charter

This document provides an overview and evidence of an EDO's Compliance Program. Below is a template with examples in italic font for your organization's EDO Compliance Program Charter.

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

The principal goal of the EDO Compliance Program is to ensure that our operations follow laws, regulations, and UnitedHealthcare policies. It helps our business activities reflect the values, integrity, and commitment to compliance that UnitedHealthcare shares with its members and stakeholders.

Responsibilities and Obligations: [outline the high-level responsibilities of the compliance program. Include the 7 elements of an effective compliance program and provide a high-level plan for their incorporation in your organization's activities.]

The EDO Compliance Program follows UnitedHealthcare's Corporate Responsibility and Compliance Program principles. It includes seven key elements to promote a culture of preventing and detecting non-compliant conduct related to government-funded healthcare programs:

1. Written policies and procedures*: Will provide guidance for employees, agents, and business partners on compliance standards and practices.*

2. Compliance Officer and Compliance Committee *- A compliance officer oversees the program, develops, monitors, and reports on it periodically and as needed to management, coordinates training, investigates compliance issues, and ensures corrective actions are taken.*

3. Effective training and education*: Every compliance program needs regular training to help everyone working for the organization understand the relevant laws, regulations, and policies applicable to their daily business activities. All employees will be trained to ensure they know the necessary laws, regulations, and best practices for a successful compliance program.*

4. Effective communication channels (including anonymous reporting): *A successful compliance program requires strong communication methods. The compliance officer is required to ensure everyone can ask questions and report issues safely, without fear of punishment.*

5. Internal monitoring and auditing: *Regular checking and evaluating our business operations will occur to ensure they are effective and compliant. Various methods will be used to monitor daily activities and practices. The information collected will be used to prevent, detect and correct any compliance risks and deficiencies identified.*

6. Disciplinary enforcement: *Depending on the severity of any compliance infractions discovered during monitoring and auditing, actions ranging from re-training up to and including termination may be taken. The disciplinary actions will be fair and consistent, based on infraction severity.*

7. Responding to and reporting problems: *If there are signs of suspected noncompliance, an investigation will be conducted to check for violations. If a violation is found, all affected parties will be informed, and efforts will be made to fix or reduce the impact of the issue.*

Structure and Membership of EDO Compliance Organizations:

- The structure of the EDO Compliance Program depends on the size and complexity of the EDO's operations.
- The program must be designed to ensure all duties and responsibilities are successfully performed.
- Key management staff will oversee the agency's efforts to meet UnitedHealthcare's contractual and business expectations.

Outline the structure of your compliance program:

- Describe the structure of your compliance program.
- List the titles or positions (individual names are not recommended) of those who will be part of your compliance committee.
- Include members from key areas within your business to ensure effective communication and oversight of all areas.

Knowledge of Regulations and UnitedHealthcare Company Policy: [Explain how you will keep up-to-date with regulatory requirements, company policies, and general compliance standards for your business.]

The EDO Compliance Program will collaborate with UnitedHealthcare to keep track of relevant policy, procedure, and regulatory documents for their marketing and sales activities. Additionally, the EDO Compliance Program will create and maintain general compliance requirements for areas like Information Security, Records Management, Privacy and Security Awareness, and Fraud, Waste, and Abuse

Oversight of EDO Compliance Program: [Use this section to describe the main processes and programs that help you oversee your organization and keep it compliant.]

UnitedHealthcare may regularly check EDO Compliance operations to monitor and audit their performance. They use standards and metrics to evaluate the effectiveness of the EDO Compliance Program, which are reported through Dashboard reports (described herein) sent to each EDO regularly.

Policies and Procedures: [Describe the organization's main policies and procedures to ensure compliance with requirements. Include key policies from the toolkit. Also, explain how the organization reviews and updates these policies annually or when changes happen, including the review and approval process and timing.]

Appendix C: P&P Sample Template

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