



Compliance Policy

for Contracted Healthcare Providers
and Third Parties

Effective January 2024

Overview

Humana has compliance program requirements for those supporting its business: your organization, its employees and downstream entities. These requirements include, but are not limited to, the core elements of Humana's Compliance Program outlined in the table of contents on the next page. Your organization may be required to provide assurance that it understands and incorporates these components into its own compliance program or that it has a materially similar program.

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Humana reviews this document annually and it contains minimal updates to what was in the 2023 version. See page 2 for clarifications.

It is important that you read this.

If you are an administrator

This document is an extension of your organization's agreement(s) with Humana or a Humana-related entity. This means your organization must comply with what is outlined within it and provide this publication or an updated, materially-similar document to all employees and third parties who support Humana's Medicare and/or Medicaid products as part of our relationship.

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Key point of notable change (and page number)

- **Cover page:** Clarified that this document is an extension of your organization’s agreement(s) with Humana or a Humana-related entity. This means your organization must comply with what is outlined within it.
- **Page 4:** *Section IV – Investigation, Discipline and Correction* – Clarified that documentation/records pertaining to reviews, investigations and actions taken pertaining to compliance and ethics issues is considered a component of oversight activities and must be retained for 10 years.

Introduction

Purpose

This policy relays Humana’s expectation that you share our commitment to conducting business ethically, with integrity, and in compliance with applicable laws, regulations, and requirements. This includes complying with the guiding principles outlined in this policy.

This policy communicates how to assure an effective compliance program and processes for fraud, waste and abuse prevention, detection, and correction, by communicating requirements of the following:

- the Centers for Medicare & Medicaid Services (CMS)
- state-specific and product-specific requirements
- Humana policies and procedures to support the requirements

Organization

The core elements of an effective compliance program are outlined in the page titled *Key takeaways from this policy*.

Clarifications and examples of the core elements are provided in the following sections after the aforementioned page to further illustrate Humana’s expectations of your organization:

- I. Framework
- II. Communication
- III. Oversight
- IV. Investigation, Discipline and Correction

Responsibility

Humana maintains ultimate responsibility for the effectiveness of its compliance program; and one way it does this is to:

- update this policy annually or when there are material regulation, policy, or guidance changes.
- require all contracted healthcare providers and third parties to adhere to and maintain policies to address the principles outlined in this document.
- expect your organization to have an effective compliance program.
- have ongoing monitoring, auditing, and reporting processes to assess your organization’s compliance.



Definitions

Associate – Refers to a Humana employee.

Audit – Refers to a formal review of compliance with a particular set of internal criteria based on applicable laws and regulations.

Centers for Medicare & Medicaid Services (CMS) – An agency within the U.S. Department of Health and Human Services that is responsible for the administration of the federal Medicare and Medicaid programs.

Conflicts of interest – Personal, familial, or business relationships that could amount to, but are not limited to:

- Competing with any of Humana’s product offerings
- Providing services to a competitor of Humana
- Interfering with the performance of work duties

Please refer to Humana’s Ethics Every Day for Contracted Healthcare Providers and Third Parties for examples.

Downstream entity – Any party with an indirect written arrangement that exists between a first tier entity and third party for providing a covered service or performing a function related to a Humana-administered Medicare Advantage, Medicare prescription drug benefit, Medicaid and/or dual Medicare-Medicaid plan. This continues to the level of the ultimate provider of a service or product.

Example: While an organization contracted directly with Humana is a first tier entity, the hospitals and healthcare practitioners contracted with the organization as part of its network are downstream entities.

FDR – A first tier, downstream or related entity of Humana supporting Humana’s products and services. This is a contracted party that performs business functions Humana is otherwise responsible for performing. Please refer to the separate definitions of first-tier, downstream and related entity, as well as healthcare providers and third parties, for clarification.

FDR employees and downstream entities – Individuals employed by, contracted with, or otherwise supporting an FDR, who are acting on behalf of Humana, either directly or indirectly. These include, but are not limited to, FDR employees, employed and contracted healthcare providers and pharmacists, board members, pharmacy and therapeutic committee members, volunteers, and consultants, as well as any other contracted individuals.

First tier entity – Any entity having a direct contract with a Humana entity to provide the covered services or perform a function related to a Medicare or Medicaid-eligible individual

under a Humana-administered Medicare Advantage, Medicare prescription drug benefit, Medicaid and/or dual Medicare-Medicaid plan.

Healthcare providers and third parties – Humana term for FDRs. Examples are delegated and non-delegated healthcare providers, delegated entities, pharmacies, sales agents, sales agencies, vendors, and suppliers of administrative goods and/or services, contractors, and delegates.

Vendors and suppliers of administrative goods and/or services are considered third parties.

Humana – Refers to Humana Inc. and its wholly-owned subsidiaries.

Monitoring – Reviews that are repeated regularly during the normal course of operations to confirm:

- Ongoing compliance even in the absence of identified problems; **or**
- Corrective actions are undertaken and effective

Related entity – Any entity that is related to Humana by common ownership or control.

Third party – Any person, organization or other entity with which Humana has a relationship to support their obligation to Humana, including vendors, subcontractors, providers, etc. Refer to separate definitions of first-tier entity, downstream entity, and related entity for further detail.

Volunteer – Any individual who performs work for Humana related to the Medicare or Medicaid program but is not employed by or contracted with Humana in any fashion, and not otherwise compensated for his/her work. An example is an unpaid student intern.



Key takeaways from this policy

This page outlines key components of Humana’s compliance program and what your organization’s compliance program must include. Clarifications and examples are on subsequent pages in sections with the same names as listed here in green.

This policy is aligned with Humana’s internal Corporate Compliance Plan. Both incorporate the seven elements of an effective compliance program outlined by CMS.

- This commitment includes having policies and procedures incorporating these elements outlined in this policy, all applicable federal and state regulations and actions needed to address them, and compliance expectations embodied in the standards of conduct.
- Your organization must share this commitment to support Medicare and/or Medicaid plans administered by Humana.

Section I – Framework

Element I: Written Policies, Procedures and Standards of Conduct

- Compliance policies and Standards of conduct

The above must be formally documented, reviewed annually, and revised/approved as needed. They must be distributed to educate employees, contractors, and subcontractors to assure sufficient performance and oversight of administrative functions and/or provided healthcare services in support of Humana’s Medicare and/or Medicaid products. They may include or reference other documents that outline protocols for relationships with downstream entities. Supporting policies and procedures must also be in place and adhere to the above review and approval timeframe.

- All must be retained for at least 10 years.

Element II: Compliance Officer, Compliance Committee and High-level Oversight

- Designated resources to fulfill compliance obligations. Responsible individual(s) must be adequately qualified, educated and trained to perform compliance functions.

Government contracts and/or government regulations outline additional, related requirements for third parties performing certain functions in support of a Medicaid and/or Medicare-Medicaid Duals plan.

Humana separately notifies impacted third parties on how to comply.

Section II – Communication

Element III: Effective Training and Education

- Must be conducted annually and be formally tracked.
 - Content covered must include compliance policies, standards of conduct, addressing fraud, waste, and abuse, and, when applicable, Medicaid-related subject matter.
 - An organization’s policies and procedure(s) must designate the audience for training, training topics, the frequency of education and how the training is tracked, and records are retained.
 - Completion timeframe requirements depend on the topics and are detailed in the full section on Page 6.

Element IV: Effective Lines of Communication

All who support Humana’s business, including governing body members, are required to report concerns of noncompliance, suspected, or detected FWA, violations of compliance policies, standards of conduct and/or applicable laws and regulations.

- An anonymous reporting method must be offered
 - The method(s) must be widely publicized.
 - Intimidation or retaliation against anyone making a good faith report of suspected violations is prohibited.

Additionally, there must be a means offered to contact your organization’s designated compliance resource(s).

Element V: Well-publicized Disciplinary Standards

- Widely publicize disciplinary standards and the requirement to report suspected violations.

Section III – Oversight

Element VI: Effective System for Routine Monitoring, Auditing, and Identification of Compliance Risks

- **Monitoring and auditing work plans** are necessary to assess compliance with this policy and related requirements. This oversight applies to the performance of functions of all supporting Humana business (employees, contractors, and downstream entities). Timely cooperation is required.
- **Reviews of exclusion lists:** Screening employees and subcontractors against the Office of Inspector General (OIG) and System for Award Management (SAM) exclusion lists must be conducted by your organization prior to hire/ contract of any party and at least monthly thereafter. An individual or entity appearing on either list must be promptly removed from supporting Humana business and this must be reported to Humana.
- **Record retention of oversight and training:** for 10 years.
- **Conflicts of interest:** Have a process to assess potential conflicts of interest and handle identified conflicts.

Section IV – Investigation, Discipline and Correction

Element VII: Procedures and System for Prompt Response to Compliance Issues

Humana investigates suspected violations, takes applicable disciplinary action, and implements any necessary corrections to prevent future violations.

Your organization must have a commitment to:

- Report to plan sponsors: a) confirmed violations related to contracted functions; and b) subsequent actions taken
- Cooperate with any investigation (of a sponsor, Humana, Humana designee or a government agency)
- Initiate disciplinary actions when applicable
- Implement corrections to prevent future violations
- Retain documentation/records pertaining to reviews, investigations and actions taken pertaining to compliance and ethics issues for 10 years
 - These actions are a component of oversight activities

I. Framework

Written Policies, Procedures and Standards of Conduct

Numerous policies, standards and procedures must exist to support these compliance program requirements. In particular:

- **Education on Requirements and Expectations**
Assuring content is in place to educate employees and downstream entities on these topics can be accomplished by adopting the following documents or maintaining documents that have materially similar content:
 - this compliance policy; and
 - Humana’s Ethics Every Day for Contracted Healthcare Providers and Third Parties (standards of conduct), which can be accessed at [Humana.com/fraud](https://www.humana.com/fraud).
- **Protocols for Relationships with Downstream Entities**
Though Humana is ultimately responsible for any functions performed to support its business, there are also certain requirements when your organization seeks to enter into a relationship with a downstream entity.
 - Notify Humana prior to subcontracting any services related to the functions your organization performs for Humana, regardless of whether the proposed work to support Humana business is to be performed onshore or offshore (outside of the United States or Puerto Rico).
 - Receive Humana approval before any offshore work begins or for any changes to an existing offshore arrangement.
 - Maintain compliant written agreements.

Medicare note: CMS requires Humana to report within 30 days of contract signature date any offshore arrangements that include contractors and/or employees that receive, process,

transfer, handle, store, or access Humana Medicare member protected health information at an offshore location in oral, written, or electronic form. Additionally, Humana must promptly report any changes in the functions or locations of offshore contractors.

Medicaid note: Certain states have prohibitions against offshoring data related to a Medicaid plan.

- Maintain policies and procedures for adequate compliance and performance oversight of the functions performed by employees, subcontractors, and downstream entities.
Examples include:
 - Conducting exclusion screening of those your organization designates to perform work in support of your organization’s contract with Humana
 - Confirming that downstream entities adhere to core compliance requirements, including all those outlined in this document (such as providing compliance policies, standards of conduct and fraud, waste, and abuse (FWA) training for, and conducting exclusion screening of, their employees and those supporting the downstream entities, and monitoring and auditing of further downstream entities)



II. Communication

Effective Training and Education

Your organization is responsible for developing training content or using another organization’s training content. Humana offers materials that can be used for many of the training requirements.

Your organization’s discretion may be used on how training and other education is administered. Examples include classroom training, online training modules or attestations that these audiences have read and received standards of conduct, compliance policies and procedures.



Regardless of the method used for training, Humana reserves the right to request proof from your organization that an applicable training or education requirement has been met. Humana may require an attestation of completion for certain training or education. This can include assurance that those your organization designates to support Humana are receiving sufficient information to meet expectations. What must be retained and would be submitted, if requested, could be tracking logs, procedures and other documentation that lists the time, attendance, topic(s) covered, certifications of completion and scores of any training and tests administered (if applicable).

Required Training and Education

In addition to training on the separate topics of general compliance and combating FWA, other training may be necessary, such as:

- Applicable, job-specific compliance training
- Training required by a government contract for a Humana Medicaid or Medicare-Medicaid Duals plan on topics such as:
 - Cultural competency
 - Health, safety, and welfare education
 - Medicaid
 - Humana orientation
- Special Needs Plan (SNP) for healthcare practitioners participating in a Medicare SNP

Sufficient understanding of training received must be demonstrated or confirmed prior to performing any functions included under a Humana contract. This may be accomplished through knowledge checks or other means.

Notes: Humana annually notifies an organization when training on topics related to Medicaid is required. Separately, when individuals have Humana system access, Humana provides FWA training to them. Therefore, Humana will monitor the completion of that FWA training for those individuals and they are not required to receive additional or separate FWA training from your organization.

Required Training Timelines

All healthcare providers and third parties that support Humana, yet do not have system access, must receive annual FWA training, while those supporting Medicaid may also need to complete additional training. Timeframes for completing training are within 30 days of hire or contract and within 30 days after assignment annually thereafter. This timing is:

- **Suggested for:** Compliance and non-Medicaid-specific FWA training
- **Required for:** Medicaid-specific topics, including FWA

Anyone assigned Humana system security access is required to take Humana’s training on ethics and compliance, including FWA, and must complete it within 30 days of receiving such access and annually thereafter. Job-specific, operational training must be provided by healthcare providers and third parties and be completed within 30 days of hire or contract to properly perform the functions required.

Effective Lines of Communication

Have an efficient means to relay necessary compliance matters. For example: Humana communicates with its associates through the company intranet to provide continual awareness of the importance of compliance. Humana also communicates regularly with its healthcare providers and third parties through a variety of methods, including contracts, administration manuals, newsletters, a compliance portal, **Humana.com**, **Availity.com**, and policy communication.

Access and Availability of Compliance Officer

Provide a means for those supporting your organization to share concerns or pose questions to compliance leadership within your organization and/or with Humana. For example: Humana’s Chief Compliance Officer, Sean O’Reilly, J.D., is available to address any suggestions or comments on maintaining ethical behavior or identifying and preventing fraudulent or criminal misconduct.

He may be contacted through the Ethics Office or the Help Line: **1-877-5-THE-KEY (1-877-584-3539)**.

Mr. O’Reilly is based in Humana’s corporate headquarters: 500 West Main St., Louisville, KY 40202.

Noncompliance with Humana’s Training Requirements

The following may occur if any Humana employee or individual supporting a healthcare provider or third-party contract is found to be noncompliant with respect to Humana’s training requirements or an individual’s singular actions demonstrate noncompliance with Humana’s compliance expectations:

- Humana will give the organization written notice of noncompliance.
- The Humana employee, healthcare provider or third party may be disciplined up to removal from supporting work for Humana.

Changes Impacting Training

Your organization must notify those impacted when there are changes to a process in a specific contract that requires immediate, job-specific training and requires your organization to act immediately to provide such training to its employees and any downstream entities. Humana does this today, typically via a notable changes section in policy and training documents.

Requirement to Report

Notable examples of compliance concerns and suspected or actual compliance and FWA violations that affect Humana-contracted work include, but are not limited to, others' actions to:

- Falsify benefit/enrollment application(s)
- Lie, using false pretenses or making false statements to get money from the healthcare system
- Provide inaccurate diagnosis code information to payors
- Use the identifying information of another person with the intent to defraud

Furthermore, policies and procedures must be in place to assure there is sufficient awareness of:

- **What to report:** suspected or detected noncompliance;
- **How to report it:** via Humana's options and/or any other method(s) your organization has in place; and
- **Why:** Review of all concerns must be conducted to assure no gaps exist and to correct discovered process issues. Disciplinary action up to termination of contract or employment can result in not reporting suspected concerns.

Methods for Reporting Suspected or Detected Noncompliance to Humana

Examples of methods offered by Humana:

- By telephone: Ethics Help Line, **1-877-5-THE-KEY (1-877-584-3539)**
- Online: Ethics Help Line Web reporting site www.ethicshelpline.com
- By email: ethics@humana.com (Ethics Office)

Suspected or detected FWA violations may also be reported directly to Humana's Special Investigations Referral department by calling **1-800-614-4126**, emailing siureferrals@humana.com, or faxing **1-920-339-3613**.

If your organization offers any method not listed above, or offers any method(s) along with any from Humana:

- The reports impacting Humana must be communicated in a timely manner to Humana by your organization's compliance resource(s).
- The reporting method(s) must share the following features offered by Humana's methods listed in the next column.

Humana expects all organizations supporting Humana have at least their own, reporting method not offered by Humana. Why? Your

organization is best equipped to handle an initial review involving someone your organization designates to support Humana business, so corresponding action can be taken in the timeliest manner. Also, any reports to Humana that do not pertain to Humana business are not in scope for Humana, which means they must not be reported to Humana.

Necessary Key Features

- **Intake neutrality.** For example: The Ethics Help Line is staffed by non-Humana personnel employed by a separate and independent company.
- **Anonymous reporting.** Humana requests that if a reporter wants to remain anonymous, processes be in place to assure he/she provides enough information to allow the issue to be investigated.
- **Status update.** Regardless of the reporting method used, the individual reporting a suspected or detected violation will receive a confidential identification number that will allow for follow-up on the status of the issue reported, along with a recommended follow-up date.

Widely publicizing methods for reporting compliance and FWA concerns and non-retaliation policy in facilities

Examples: posters, intranet sites, mouse pads, key cards, and other prominent displays.

Addressing noncompliance with Requirements

If a healthcare provider or third party discovers noncompliance with any requirement, including training, the healthcare provider or third party must:

- a) Initiate disciplinary action that may include issuance of a corrective action plan or termination of the employee or downstream entity; and
- b) Notify Humana.

III. Oversight

Compliance Officer and Compliance Committee, and High-level Oversight

Humana is not prescriptive regarding specific qualifications; however, organizations may choose to consider qualifications such as formal education, on-the-job training, industry experience, compliance experience, continuing education, conferences, and seminars in determining adequacy.

Example compliance resource

Humana has a chief compliance officer (CCO) who is a full-time Humana associate. The CCO:

- Participates on company compliance committees and reports on the state of compliance matters to the audit committee of the board of directors; and
- Reports indirectly to the chief executive officer (CEO) and reports administratively to the chief risk officer.

The CCO, chairperson of the board, CEO, and the board of directors provide overall leadership and governance for the corporate compliance plan.

Monitoring and Auditing Work Plan(s)

Humana has sufficient oversight plans and mechanisms to monitor your organization’s compliance obligations. Methods include periodically asking a third party designated to support Humana business to complete a self-assessment questionnaire, or survey, submit documentation, and/or attest to applicable policy, procedure, and compliance requirements. A common method also performed is an on-site or desktop audit, which may include inspection of the facilities, systems, books, procedures, audit work plans, results, and records that relate to the services provided under the contractual agreement. When Humana notifies your organization that an oversight activity is being conducted, your organization must provide timely turnaround of these requests in accordance with the time period specified by Humana.

Disciplinary actions could result from conducted monitoring and auditing initiatives. These could include but are not limited to mandatory (re)training, corrective action plans tracked to closure or contract termination. Your organization must have policies and processes to assure such action is taken when it conducts oversight.

Conflicts of Interest

Identified conflicts of interest must be removed or approval to continue work can be granted despite the conflicts.

e.g., A family member working for a competitor of your organization or of Humana is not a guarantee that the employee will engage in anti-competitive behavior or seek to commit fraud, etc.

However, your organization must comply with the following, if requested by Humana:

- Provide information on conflicts of interest; and
- Remove conflicts to assure contractual obligations to Humana continue to be met, and, if necessary, remove the person or entity that was performing any function(s) in support of Humana.

IV. Investigation, Discipline and Correction

Violation of requirements outlined in Humana’s standards of conduct (Ethics Every Day for Contracted Healthcare Providers and Third Parties), or a materially similar policy your organization has in place, as well as in relation to other policies and procedures could compromise Humana’s integrity and reputation. A violation may also result in a required corrective action, termination of contract and/or reporting of the violation to appropriate regulatory and/or law enforcement authorities.

Your organization must share Humana’s commitment to initiate investigations of any reports of suspected or detected violations of Humana policies and procedures, or materially similar policies your organization has in place, as well as suspected FWA. This must be conducted as quickly as possible, but not later than within two weeks of identifying the suspected or detected issue. All reported issues must be treated confidentially to the greatest extent possible, and documentation is maintained.



If corrective actions required by Humana or by your organization for a party your organization designates, monitoring and/or auditing the party with a deficiency is necessary to confirm that corrective actions have been implemented. Oversight following implementation of the corrective action must also occur, as appropriate, to facilitate ongoing, effective corrective actions.

Widely publicize disciplinary standards and the duty to report suspected noncompliant and unethical behavior and FWA.

Example methods include newsletters, regular presentations and department staff meetings, communications with downstream entities, general compliance training, intranet site and posters prominently displayed throughout employee work and break areas.

- Take prompt disciplinary action when there is noncompliant or unethical behavior by their employees or downstream entities or FWA may also include issuing corrective action plans that must be tracked to closure.

Appendices

Appendix A: Resources

<p>Federal Register – Medicare Program; Contract Year 2019 Policy and Technical Changes</p>	<p>Issued in April 2018, this outlines many revisions to government regulations for 2019 onward. The core changes for compliance programs are the removal of the requirement for sponsors like Humana to: a) provide training to healthcare providers and third parties on general compliance and combating FWA and b) confirm completion of that training. However, Humana continues to require all healthcare providers and third parties to: 1) annually train those supporting Humana on FWA, although use of CMS material is not required; 2) have a compliance program; and 3) annually provide corresponding policies and standards of conduct to those supporting them. No longer must these activities also occur within 90 days of contract/hire. Your organization should review the government document for other impacts.</p> <p>https://www.gpo.gov/fdsys/pkg/FR-2018-04-16/pdf/2018-07179.pdf</p>
<p>OIG Special Advisory Bulletin on Exclusion</p>	<p>Issued in May 2013, this answers common questions on this topic, including screening frequency, liability, how exclusions can be violated, and the administrative sanctions OIG can pursue against those who violated an exclusion.</p> <p>http://oig.hhs.gov/exclusions/files/sab-05092013.pdf</p>
<p>CMS Compliance Program Policy and Guidance</p>	<p>This site lists compliance program regulations and includes select CMS memoranda serving as the basis for requirements and provides materials and a CMS contact email address to leverage for training and support. The Related Links section of this web page includes Chapters 9 of the Prescription Drug Benefit Manual and 21 of the Medicare Managed Care Manual.</p> <p>https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ComplianceProgramPolicyandGuidance</p>
<p>Ethics Every Day for Contracted Healthcare Providers and Third Parties</p>	<p>http://apps.Humana.com/marketing/documents.asp?file=1112774</p>
<p>Compliance Program Toolkit</p>	<p>Humana offers an electronic Compliance Toolkit to support healthcare providers and third parties in compliance program enhancement and maturity.</p> <p>Submit related inquiries to: ThirdPartyFDRCompliance@humana.com</p>

Appendix B: Summary of Applicable Laws and Regulations

Note: Depending on the function your organization performs, not all of the following laws and regulations may be applicable to it.

<p>Title XVIII of the Social Security Act</p>	<p>Passed in 1965, the Social Security Act included Title XVIII, which became known as Medicare. Title XVIII includes Part A, which provides hospital insurance for the aged and disabled, and Part B, which provides medical insurance. To address the Part A and Part B benefits, Medicare offers a choice between an open-network single payer healthcare plan (known as Original Medicare) and plans administered by private companies approved by Medicare (Medicare Advantage, or Medicare Part C), in which the federal government pays for private companies to administer health coverage. Medicare Part D covers outpatient prescription drugs exclusively through plans offered by Medicare-approved private insurance companies. Part D plans can either be stand-alone prescription drug plans or included in a Medicare Advantage plan that offers prescription drugs. Humana offers Part C and D plans.</p> <p>Therefore, the laws and regulations related to Part C and D plans, many of which are listed in the link below, impact your relationship with Humana.</p> <p>http://www.ssa.gov/OP_Home/ssact/title18/1800.htm</p>
<p>Regulations governing Medicare Parts C and D, and Medicaid, where applicable, found at 42 C.F.R. §§ 422 and 423, respectively</p>	<p>CCMS has outlined compliance program guidelines in its Prescription Drug Benefit Manual, Chapter 9, and Medicare Managed Care Manual, Chapter 21. The dual-purpose CMS document is an interpretation of the compliance program requirements and related provisions in 42 C.F.R. Parts 422 and 423 for Medicare Advantage Organizations (MAO) and Medicare Prescription Drug Plans (PDP). As a result, Humana’s compliance program incorporates the seven elements of an effective program as outlined by CMS.</p> <p>42 C.F.R. § 422.503: https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-422/subpart-K/section-422.503</p> <p>42 C.F.R. § 422.504: https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-422/subpart-K/section-422.504</p> <p>42 C.F.R. § 423.504: https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-423/subpart-K/section-423.504</p>
<p>Medicare Managed Care Manual, Chapter 3 – Medicare Marketing Guidelines</p>	<p>The marketing guidelines reflect CMS’ interpretation of the marketing requirements and related provisions of the Medicare Advantage and Medicare Prescription Drug Benefit rules (42 C.F.R. Parts 422 and 423). For specific information on marketing guidelines related to providers, please refer to section 70.11 titled “Marketing in the Healthcare Setting.”</p> <p>https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/FinalPartCMarketingGuidelines.html</p>

Appendix B: Summary of Applicable Laws and Regulations

<p>Patient Protection and Affordable Care Act (Pub. L. No. 111-148, 124 Stat. 119)</p>	<p>This extensive act is most known for the increased rights and protections it established for consumers, but it has many provisions, known as titles. The core elements of this act include, but are not limited to, the following:</p> <ul style="list-style-type: none"> • Where/how to purchase coverage was expanded • New benefits became available for those eligible for coverage • There were shifts in who is eligible for receiving and retaining coverage and under what arrangements • Organizations offering insurance, like Humana, became subject to greater accountability <p>The act affected payment (amounts) and reimbursement(s) for certain benefits, and increased the ability to appeal claims, which may impact enrollment and claims processing. Humana complies with the act, which also may have affected how your organization maintains records and/or tracks payments.</p> <p>There are other titles that could also impact your organization, but not directly regarding Humana. The act is available here for review:</p> <p>http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf</p>
<p>Federal Acquisition Regulation</p>	<p>This regulation prohibits gifts with greater than \$15 fair market value from being given to, or received from, the government. The exceptions are:</p> <ul style="list-style-type: none"> • Modest items of snacks and refreshments (such as soft drinks, coffee, and donuts) offered other than as part of a meal if made available to everyone in attendance • Promotional or marketing materials (e.g., pens, pencils, note pads and calendars) valued at \$15 or less • Tokens of appreciation (e.g., command coins or patches) with a logo, valued at \$15 or less
<p>Health Insurance Portability and Accountability Act (HIPAA) (Public Law 104-191)</p>	<p>Per the U.S. Department of Labor, HIPAA was initially passed in 1996 to “improve portability and continuity of health insurance coverage.” As a result, there are more consumer protections regarding options for coverage.</p> <p>http://aspe.hhs.gov/admsimp/pl104191.htm</p> <p>Later “rules,” or provisions, were passed in 2001 and 2003 to protect the privacy, confidentiality, and security of individually identifiable health information. This includes the establishment of security standards for electronic protected health information.</p> <p>Your organization and Humana must have sufficient safeguards regarding this type of information, including who may access it, how much of it may be accessed by any individual and how it is retained and transmitted. See summaries below:</p> <p>HIPAA Privacy Rule: http://www.hhs.gov/hipaa/for-professionals/privacy/index.html</p> <p>HIPAA Security Rule: http://www.hhs.gov/hipaa/for-professionals/security/index.html</p>
<p>False Claims Acts (31 U.S.C. §§ 3729-3733)</p>	<p>This act gives the federal government leverage against persons/entities involved in fraudulent activities with the government. This allows financial liability in the form of a civil penalty and damages to be imposed for submitting, or causing someone to submit, a false or fraudulent claim for government payment.</p> <p>https://www.govinfo.gov/content/pkg/USCODE-2019-title31/pdf/USCODE-2019-title31-subtitleIII-chap37-subchapIII-sec3729.pdf</p> <p>https://www.govinfo.gov/content/pkg/USCODE-2019-title31/pdf/USCODE-2019-title31-subtitleIII-chap37-subchapIII-sec3730.pdf</p> <p>https://www.govinfo.gov/content/pkg/USCODE-2019-title31/pdf/USCODE-2019-title31-subtitleIII-chap37-subchapIII-sec3731.pdf</p> <p>https://www.govinfo.gov/content/pkg/USCODE-2019-title31/pdf/USCODE-2019-title31-subtitleIII-chap37-subchapIII-sec3732.pdf</p> <p>https://www.govinfo.gov/content/pkg/USCODE-2019-title31/pdf/USCODE-2019-title31-subtitleIII-chap37-subchapIII-sec3733.pdf</p> <p>An individual with knowledge of fraud against the government may file a lawsuit (plaintiff) on behalf of the government against the person or business that committed the fraud (defendant). The filer of the lawsuit is also known as a “whistle blower.”</p> <ul style="list-style-type: none"> – Retaliation against individuals for investigating, filing, or participating in a whistle blower action is prohibited. – If the action is successful, the plaintiff is rewarded with a percentage of the recovery. <p>Please note: The state of Florida has a statute similar to the Federal False Claims Act that allows for the recovery of Medicaid funds, albeit by the state of Florida.</p>
<p>Federal Criminal False Claims Statutes (18 U.S.C. §§ 287,1001)</p>	<p>Section 1001 applies to anyone whose action(s) related to any claim(s) for government payment consist(s) of any of the following:</p> <ul style="list-style-type: none"> • Falsifying, concealing, or covering up by any trick, scheme or device, a material fact related to any claim(s) for government payment; • Making any materially false, fictitious, or fraudulent statement or representation; • Making or using any false writing or document knowing it contains any materially false, fictitious, or fraudulent statement or entry. <p>Section 287 states that whoever makes or presents to the government a claim knowing that it is false, fictitious, or fraudulent, shall be imprisoned and subject to fines. The government is required to establish all of the following in regard to the action(s) of a false claim(s) case defendant. He/she:</p> <ul style="list-style-type: none"> • Made or presented a false, fictitious, or fraudulent claim to a department of the United States; • Knew the claim was false, fictitious, or fraudulent; and

	<ul style="list-style-type: none"> • Did so with the specific intent to violate the law or with awareness that what s/he was doing was wrong. http://www.gpo.gov/fdsys/pkg/USCODE-2011-title18/pdf/USCODE-2011-title18-part1-chap15-sec287.pdf http://www.gpo.gov/fdsys/pkg/USCODE-2011-title18/pdf/USCODE-2011-title18-part1-chap47-sec1001.pdf
Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b))	<p>This federal statute prohibits any individual or entity from knowingly and deliberately offering, giving, or receiving money or something of value in exchange for referrals of healthcare goods or services that will be paid for in whole or in part by a federal healthcare program, such as Medicare or Medicaid.</p> <p>http://www.ssa.gov/OP_Home/ssact/title11/1128B.htm#f</p>
The Beneficiary Anti-Inducement Statute (42 U.S.C. § 1320a-7a(a)(5))	<p>This federal statute declares that any person who gives or offers to give anything of value* to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence a beneficiary’s choice of a particular healthcare provider, practitioner or supplier to buy or rent a Medicare or Medicaid covered item from the provider, practitioner or supplier may be liable for civil money penalties of up to \$10,000 for each wrongful act. https://www.govinfo.gov/content/pkg/USCODE-2019-title42/pdf/USCODE-2019-title42-chap7-subchapXI-partA-sec1320a-7a.pdf</p>
OIG General Policy Statement Regarding Gifts (Note: Humana has Medicaid contracts with state agencies that could have different gift policies. Email questions to the Ethics Office at ethics@humana.com)	<p>*The OIG stated in guidance that there is a “nominal value” exception that allows a person to give:</p> <ul style="list-style-type: none"> • A gift to a beneficiary as long as the gift has a retail value of \$15 or less • Multiple gifts each with retail value of \$15 or less over a 12-month period, as long as the total retail value of the gifts does not exceed \$75 <p>Any such gift must not be in cash or cash equivalents, so it must not be a gift card or gift certificate. The nominal value amounts above are detailed in the OIG general policy statement below that updates amounts listed in a prior Special Advisory Bulletin from the OIG.</p> <p>https://oig.hhs.gov/fraud/docs/alertsandbulletins/OIG-Policy-Statement-Gifts-of-Nominal-Value.pdf</p>
Prohibitions against employing or contracting with persons or entities that have been excluded from doing business with the federal government (42 U.S.C. §1395w-27(g)(1)(G))	<p>The expectations of CMS and Humana in regard to screening government exclusion lists are outlined in the oversight section on Page 9 of this policy and in this federal provision: https://www.govinfo.gov/content/pkg/USCODE-2019-title42/pdf/USCODE-2019-title42-chap7-subchapXVIII-partC-sec1395w-27.pdf</p>
Foreign Corrupt Practices Act (FCPA)	<p>This federal statute prohibits giving any type of gift, payment, entertainment, gratuity or anything of value to a foreign official, political candidate, political party, party official, public international organization, their employees or their representatives or entities working with them for the purpose of obtaining, retaining or directing their business to any person for the purpose of influencing an official act or decision or securing an improper advantage. The FCPA has specific criminal and civil penalties for violations: fines for the responsible organization, suspension, or debarment from participation in federal programs and fines and imprisonment for individuals convicted of such conduct.</p> <p>https://www.justice.gov/criminal-fraud/foreign-corrupt-practices-act</p>
Civil monetary penalties of the Social Security Act (42 U.S.C. § 1395w-27 (g))	<p>This provision of the Social Security Act describes the penalties that can be assessed to organizations that offer Part C and/or Part D plans should CMS determine they do not meet the requirements outlined in their contract(s) with CMS. Your organization is affected by this act if it supports and/or sells any of Humana’s Medicare Advantage or prescription drug products. Examples of such impactful provisions include, but are not limited to:</p> <ul style="list-style-type: none"> • Enrolling an individual in any such plan without the prior consent of the individual or the individual’s designee • Failing to re-enroll an eligible individual • Denying or discouraging an eligible individual from plan enrollment • Noncompliance with marketing restrictions surrounding these plans • Failing substantially to provide medically necessary items and services that are required (under law or contract) to an individual covered under the contract <p>https://www.govinfo.gov/content/pkg/USCODE-2019-title42/pdf/USCODE-2019-title42-chap7-subchapXVIII-partC-sec1395w-27.pdf</p>
Physician Self-referral (“Stark”) Statute (42 U.S.C. § 1395nn)	<p>This statute:</p> <ul style="list-style-type: none"> • Prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership, investment, or compensation), unless an exception* applies • Prohibits the entity from presenting, or causing to be presented, claims to Medicare (or billing another individual, entity, or third-party payer) for those referred services <p>* Specific exceptions have been established, and the federal government has the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse.</p> <p>Please refer to the following link for a list of the established exceptions and additional information: https://www.cms.gov/PhysicianSelfReferral/</p>
Fraud and Abuse, Privacy and Security Provisions of the Health Insurance Portability and Accountability Act, as modified by HITECH Act	<p>This act could be considered an extension of HIPAA, as it enables the U.S. Department of Health and Human Services to promote and expand the adoption of health information technology. It addresses:</p> <ul style="list-style-type: none"> • Use of electronic health records, including incentives for adopting them and requirements around their disclosure • How to secure protected health information appropriately • When and to whom notifications should be made in regard to data breaches of unsecured protected health information (PHI) <p>http://www.healthit.gov/policy-researchers-implementers/health-it-legislation-and-regulations</p>

Fraud Enforcement and Recovery Act of 2009	<p>This act improves the enforcement of various kinds of fraud related to federal assistance and relief programs, the recovery of funds lost to these frauds, and for other purposes. It increased resources for investigation and prosecution of fraud cases and made recovery under the False Claims Act, 31 USC § 3729 statute easier.</p> <p>http://www.gpo.gov/fdsys/pkg/PLAW-111publ21/pdf/PLAW-111publ21.pdf</p>
CMS Data Use Agreement	<p>Humana’s Compliance Policy and Ethics Every Day for Contracted Healthcare Providers and Third Parties incorporate the overarching aspects of the CMS Data Use Agreement to facilitate the proper safeguarding of all data, including CMS-related data, by Humana and healthcare providers and third parties, regardless of whether support is provided for Humana’s Part C and/or Part D offerings.</p> <p>The overarching components of the CMS Data Use Agreement are as follows:</p> <p>Disclosure, use, or reuse of the data covered by the agreement between CMS and Humana must only be for the purpose(s) specified within the agreement, unless CMS provides appropriate authorization for any other purpose(s).</p> <ul style="list-style-type: none"> • Any individual’s access to the data must only be on a need-to-know basis. • Data access must be limited to the minimum amount of data and minimum number of individuals necessary to achieve the purpose stated in the agreement. <p>Sufficient Data Safeguards for the storage and disclosure of data/information must be established from the following perspectives: administrative, technical, and physical. Together, these measures ensure data confidentiality is protected and that unauthorized use or access to it is prevented.</p> <p>Handling of Suspected or Detected Breaches</p> <ul style="list-style-type: none"> • This matter is addressed in the Effective Communications section of this policy under “Methods for Reporting Suspected or Detected Noncompliance to Humana.” <p>A signed CMS Data Use Agreement provides CMS with assurance of compliance with the requirements of the Privacy Act, the Privacy Rule, and CMS data release policies when CMS data is used by anyone outside of CMS. The agreement must be completed and updated when applicable by Humana. Upon CMS’ receipt of the completed agreement, CMS provides Humana with, and/or access to, data containing, but not necessarily limited to, protected health information and individual identifiers from CMS’ Systems of Record. You are responsible for consulting your legal counsel to determine when/if there are instances of the CMS Data Use Agreement applies to your organization.</p>
All sub-regulatory guidance produced by CMS and HHS, such as manuals, training materials, HPMS memos and guides	<p>Vast guidance resources are available on the following websites:</p> <p>CMS: https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Guidance.html https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions</p> <p>U.S. Department of Health and Human Services: http://www.hhs.gov/ http://www.hhs.gov/regulations/index.html</p>
Annual review, update and approval deployment of compliance policies and procedures, including the standards of conduct	<p>This federal government requirement also applies to organizations and those supporting them in meeting contractual obligations to Humana.</p> <p>C.F.R. §§ 422.503(b)(4)(vi)(B) https://www.govinfo.gov/content/pkg/CFR-2020-title42-vol3/pdf/CFR-2020-title42-vol3-sec422-503.pdf</p> <p>C.F.R. §§ 423.504(b)(4)(vi)(B) https://www.govinfo.gov/content/pkg/CFR-2020-title42-vol3/pdf/CFR-2020-title42-vol3-sec423-504.pdf</p>

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