

# Compliance Policy

For Contracted Healthcare Providers and Third Parties



Effective January 2026

## 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.

Humana reviews this document annually and it contains minimal clarifications to what was in the 2025 version.  
*See page 2.*

*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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<b>Key takeaways from this policy</b>	3 - 4	<b>Notable changes</b> <i>Key points by page number</i>
<ul style="list-style-type: none"> <li>• Purpose</li> <li>• Organization</li> <li>• Responsibility</li> <li>• Policy(s) to Use</li> </ul>		Along with clarifications of Humana's Compliance Program, there are some important changes.
<b>Definitions</b>	4	<b>3-4: Key Takeaways</b>
<b>Elements (of an Effective Compliance Program)</b>	5 - 8	<ul style="list-style-type: none"> <li>• <b>Purpose:</b> Clarified that business must also include compliance with regulatory guidance</li> <li>• <b>Policy(s) to Use:</b> Added this section to clarify what policies can be used to meet requirements outlined in core Humana <u>policies like this one, and which components</u> require separate, written, non-Humana policy(s).</li> <li>• Reiterated what must be in place when utilizing downstream entities.</li> <li>• Clarified that Humana can provide some separate materials to assist an FDR with meeting one requirement or more.</li> </ul>
<b>I Written Policies, Procedures and Standards of Conduct</b>		<b>4: Definitions</b>
<b>II Compliance Officer and Compliance Committee, and High-level Oversight</b>		<ul style="list-style-type: none"> <li>• <b>Downstream entity, First Tier and Related entity:</b> CMS definitions are now used, yet clarified that Downstream entity uses an example provided by Humana.</li> <li>• <b>Healthcare providers and third parties:</b> Clarified that subcontractors can also exemplify these.</li> <li>• <b>Medicaid Subcontractor:</b> Added.</li> </ul>
<b>III Effective Training and Education</b>		<b>6: Elements</b>
<ul style="list-style-type: none"> <li>• Process and Required Content</li> <li>• Required Training Timelines</li> </ul>		<ul style="list-style-type: none"> <li>• Reiterated that it is permissible to adopt Humana's policy(s) to meet Element I for some compliance program components. Clarified that trainings on the following, separate topics also are necessary when the Medicaid line of business is supported: General Compliance and FWA.</li> </ul>
<b>IV Effective Lines of Communication</b>		<b>7: Elements</b>
<ul style="list-style-type: none"> <li>• Requirement to Report and Receive Concerns</li> <li>• Supporting Policies and Procedures</li> <li>• Methods for Reporting</li> <li>• Examples of what must be Reported</li> <li>• Addressing Noncompliance with Requirements</li> </ul>		<ul style="list-style-type: none"> <li>• Updated Chief Compliance Officer</li> </ul>
<b>V Well-publicized Disciplinary Standards</b>		<b>8: Elements</b>
<b>VI Effective System for Routine Monitoring, Auditing, and Identification of Compliance Risks</b>		<ul style="list-style-type: none"> <li>• Clarified that: a) compliance policies must be approved on an annual basis, and revised-then-approved as needed between annual approvals; b) if your organization uses downstreams to support Humana, then oversight mechanisms must be in place to monitor their compliance programs</li> </ul>
<ul style="list-style-type: none"> <li>• Monitoring and Auditing Work Plans</li> <li>• Reviews of Government Exclusion Lists</li> <li>• Conflicts of Interest</li> </ul>		<b>9: Protocols for relationships with downstream entities</b>
<b>VII Procedures and System for Prompt Response to Compliance Issues</b>		<ul style="list-style-type: none"> <li>• Clarified that offshoring work also may not be permissible when an integrated D-SNP is supported.</li> </ul>
<b>Appendices</b>	9 - 12	
<b>A: Resources</b>		
<b>B: Summary of Applicable Laws and Regulations</b>		

# Key takeaways from this policy

## 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, regulatory guidance and requirements. This includes complying with the guiding principles outlined in this policy.

This policy communicates how to assure an effective compliance program with processes for noncompliance, fraud, waste and abuse (FWA) prevention, detection, and correction, by relaying 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



**Note:** CMS gives plan sponsors the authority to implement compliance programs addressing the risks that are inherent and sponsor-specific in conducting business with the support of FDRs.

## Organization

This policy was developed based on the core compliance program requirements outlined by CMS, which apply to plan sponsors (Humana) and their FDRs. This means adhering to the 7 elements for ongoing compliance by:

- having a written, compliance program framework of policies and corresponding processes
- assuring the communication of compliance program requirements and standards of conduct
- conducting oversight of all supporting a plan sponsor
- taking timely action to prevent, detect, investigate and correct noncompliance, FWA
- taking disciplinary action when necessary and alerting Humana as applicable.

## 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 and Humana's Ethics Every Day for Contracted Healthcare Providers and Third Parties (EED).
- relay the expectation that your organization has an effective compliance program.
- have ongoing monitoring, auditing, and reporting processes to assess the compliance of your organization.

## Policy(s) to Use

Your organization may have materially-similar written policy(s) to meet requirements outlined in this policy and Humana's EED. It also may adopt either or both of these Humana policies to meet most of the components they separately outline.

However, your organization must have its own corresponding processes and written policies to meet the following obligations:

- Offering a 24/7 method to allow employees and contractors to anonymously report concerns about noncompliance, fraud, waste or abuse
- Requirement to report at an organization level (vs. by separate individuals) all identified compliance violations, fraud, waste and abuse to a plan sponsor (like Humana) when the violations do impact that sponsor
- Prohibition against intimidation and retaliation
- Widely communicating across the organization what the disciplinary standards are for addressing compliance violations, fraud, waste and abuse
- Compiling, reviewing and making determinations on possible and actual conflicts of interest

**Note:** Your organization is also required to follow other Humana policies as directed by Humana that relate to the function(s) your organization is contracted to perform for Humana.

**Additionally, if your organization contracts with downstream entities to fulfill contractual obligations to Humana, your organization must:**

- Implement an annual oversight plan
- Train them on combatting FWA, or getting annual assurance they are conducting upon hire and annually
- Distribute standards of conduct and compliance policy(s) to them upon contract and annually thereafter

- Conduct screening for active exclusions published on OIG and GSA/SAM lists upon contract and monthly thereafter
- Identify and relay when offshore arrangement is in place and/or is being sought

# Definitions

**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 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 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.

**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** – First Tier, Downstream or Related Entity. Please refer to the separate definitions of first tier, downstream and related entity.

**FDR employees** – Individuals employed by, contracted with, or otherwise supporting an FDR, who are providing health or administrative services on behalf of Humana, either directly or indirectly.

**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.

**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, as well as contractors, subcontractors 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.

**Medicaid Subcontractor** – Third party entities contracted by Humana and approved by the relevant state agencies to perform functions or provide services related to securing or fulfilling Humana's obligations under its state Medicaid contracts.

**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 an MAO or Part D sponsor by common ownership or control and:

- (1) Performs some of the MAO 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 MAO or Part D plan sponsor at a cost of more than \$2,500 during a contract period.

# Elements

## Element I: Written Policies, Procedures and Standards of Conduct

- Must be formally documented, reviewed and approved on an annual basis, and revised-then-approved as needed between annual approvals.
  - Supporting procedures must also be in place and adhere to the regular review and approval.
- Must contain content that is materially similar to this policy and Humana's Ethics Every Day for Contracted Healthcare Providers and Third Parties, accessible at [Humana.com/fraud](https://Humana.com/fraud)
  - Your organization may adopt Humana's Compliance Policy and/or Ethics policy. However, your organization must have certain policies in place in addition to Humana's Compliance Policy and Ethics Every Day. See the Key takeaways section on pages 3 and 4 for a list.
- Must be retained for at least 10 years.
- Must be distributed to employees, contractors, and downstreams who support Humana's Medicare and/or Medicaid products. Distribution must occur within 90 days of hire or contract, when there are updates to the policies, and annually thereafter.



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

Designate personnel to fulfill compliance obligations.

Responsible individual(s) must be adequately qualified, educated and trained to perform compliance functions. This includes having a 'compliance contact': someone authorized to respond to requests for assurance of compliance.

## Element III: Effective Training and Education

- Must be formally tracked.
- Content covered must include compliance policies, standards of conduct, addressing fraud, waste, and abuse (FWA), and, when applicable, Medicaid-related subject matter.
- Your organization's policies and procedure(s) must designate the audience for training, training topics, the frequency of

training, how the training is tracked, and how training records are retained

- Your employees and downstreams that support Humana must receive FWA and general compliance training and your organization must be able to demonstrate that training requirements have been fulfilled.
- The training must be completed within 90 days of hire or contract and annually thereafter
- Training records must be maintained for at least 10 years

### General compliance training should include:

- A description of your organization's compliance program, including a review of compliance policies and procedures, and the Standards of Conduct
- An overview of how to report suspected or detected noncompliance and should emphasize confidentiality, anonymity, and non-retaliation for compliance related questions or reports of suspected or detected noncompliance or potential FWA
- The requirement to report actual or suspected Medicare or Medicaid program noncompliance or potential FWA to the sponsor (Humana)
- Examples of reportable noncompliance that an employee might observe
- A review of the disciplinary guidelines for non-compliant or fraudulent behavior or when knowledge of a possible violation is not reported
- Attendance and participation in compliance and FWA training programs as a condition of continued employment/contract;
- A review of potential conflicts of interest and your organization's system for disclosure of conflicts of interest

### FWA training must include:

- Laws and regulations related to Medicare Advantage, Part D or Medicaid FWA (e.g., False Claims Act, Anti-Kickback statute, HIPAA, HITECH, etc.)
- Obligations to have appropriate policies and procedures to address FWA
- Processes to report suspected FWA
- Protections for employees who report suspected FWA
- Types of FWA that can occur in the settings in which the contracted functions are performed

Your organization's discretion may be used on how training and other education is administered. Examples include classroom training, online training modules or attestations to certify 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 organizational-level 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 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).

#### **Element IV: Effective Lines of Communication**

Your organization must have methods in place to quickly and efficiently relay necessary compliance matters.

Examples include: intranet posts, emails, newsletters, administration manuals, and a dedicated training portal.

##### **Requirement to report and receive concerns:**

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. Your organization must have a system in place to receive, record, respond to and track reports of suspected or detected noncompliance or potential FWA.

- An anonymous reporting method must be offered.
  - The method(s) available to report compliance or FWA concerns and the non-retaliation policy must be widely communicated.
  - The reporting mechanism must be available 24 hours a day.

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

All organizations supporting Humana are expected to offer 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.

Widely communicate methods to report compliance and FWA concerns. Example methods to communicate the information: posters, intranet sites, mouse pads, key cards, and other prominent displays.

Please note: Humana's Chief Compliance Officer, Susan Crowe, J.D., is available to address any suggestions or comments on maintaining ethical behavior or identifying and preventing fraudulent or criminal misconduct.

**Supporting 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. Not reporting suspected concerns can result in disciplinary action up to termination of contract or employment.

#### **Methods for Reporting Suspected or Detected Noncompliance and FWA to 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](http://www.ethicshelpline.com)
- **By email:** [ethics@humana.com](mailto: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](mailto:siureferrals@humana.com), or
- faxing **1-920-339-3613**.

##### **Examples of what must be reported**

Notable examples of 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

Compliance and/or FWA issues that do not pertain to Humana must not be reported to Humana.

#### **Addressing noncompliance with Requirements**

If your organization identifies noncompliance with any requirement, including training, your organization 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 of findings and subsequent actions that impact Humana. This must be communicated in a timely manner to Humana by your organization's compliance resource(s).

## Element V: Well-publicized Disciplinary Standards

Your organization must implement disciplinary policies that reflect clear and specific disciplinary standards.

Policies must describe expectations for the reporting of compliance issues, that employees participate in required training, and the expectation for assisting in the resolution of reported compliance issues. Additionally, the disciplinary policies must identify noncompliant, unethical, or illegal behavior through examples of violative conduct.

Disciplinary actions to take and that must be communicated are completion of additional training or retraining, issuing corrective action plans that must be tracked to closure, as well as removal from performing a function or termination of employment or contract.

The disciplinary action must be appropriate to the seriousness of the violation.

Disciplinary standards must be communicated on an ongoing basis, not simply during an initial or annual training or in policies that not all may receive. Example communication methods include: newsletters, regular presentations and as an agenda item in staff meetings, communications with downstream entities, general compliance training, as well as prominently displaying the information on an intranet site and posters throughout work and break areas.

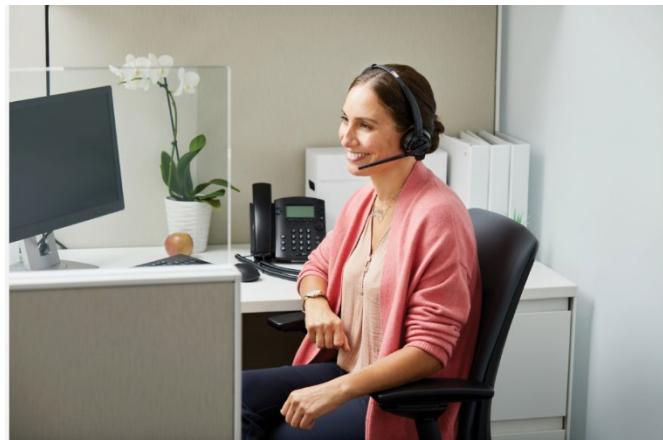
Records of all compliance violation disciplinary actions must be maintained for a period of 10 years.

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

### Monitoring and auditing work plans:

Humana has oversight work plans and mechanisms in place to monitor the performance of its first tier entities' compliance program. Methods may include periodically asking your organization's compliance contact to complete an assessment, questionnaire, or survey, to submit documentation, and/or attest to applicable policy, procedure, and compliance requirements. Additionally, Humana will conduct audits of its first tier entities to ensure compliance with all applicable laws and regulations, including ensuring that the first tier entities are monitoring compliance of downstream entities. Audit activities 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.

If your organization contracts with downstream entities to perform administrative services or healthcare services related to a Humana Medicare Advantage or Medicare prescription drug plan, your organization must have oversight mechanisms in place to monitor the downstream entities' compliance program.

**Reviews of Government exclusion lists:** Screening employees and downstream entities that support Humana 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 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.

Records of screening results must be retained for at least 10 years.

**Conflicts of interest:** Your organization must have a policy in place that addresses how to report potential conflicts of interest and how identified conflicts will be resolved or managed.

If requested by Humana, your organization must:

- 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 from Humana related work.

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

Humana may take disciplinary action as a result of 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:

- a) have a policy and procedure in place to address how suspected or detected compliance and FWA issues are investigated and resolved. An inquiry must be initiated as quickly as possible, but not later than two weeks after identifying the potential noncompliance or FWA issue.
- b) 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.
  - 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

Humana also investigates suspected violations, takes applicable disciplinary action, and implements any necessary corrections to prevent future violations. A violation may also result in reporting of the violation to appropriate regulatory and/or law enforcement authorities.

- These actions are a component of oversight activities

## Protocols for relationships with downstream entities

- Humana must be notified prior to subcontracting any services related to the functions your organization performs for Humana, regardless of whether the proposed work is to be performed onshore or offshore (outside of the 50 United States or one of the United States Territories:  
American Samoa, Guam, Northern Marianas, Puerto Rico, and the U.S. Virgin Islands
- Compliant written agreements must be in place

CMS requires Humana to report within 30 days of contract signature date any work performed for Humana by persons located in an offshore location that involves receiving, processing, transferring, handling, storing, or accessing Humana Medicare member protected health information (PHI) in oral, written, or electronic form. Additionally, Humana must report within 5 months any changes in the functions being performed offshore or locations of offshore work previously reported to CMS.

### Medicaid note:

Certain states prohibit offshoring of services, functions, or data related to a Medicaid plan or an integrated D-SNP. Any offshoring pertaining to a Medicaid plan or D-SNP must be pre-approved by Humana on a state-by-state basis.

# Appendices

## Appendix A: Resources

<b>Federal Register – Medicare Program; Contract Year 2019 Policy and Technical Changes</b>	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. <a href="https://www.gpo.gov/fdsys/pkg/FR-2018-04-16/pdf/2018-07179.pdf">https://www.gpo.gov/fdsys/pkg/FR-2018-04-16/pdf/2018-07179.pdf</a>
<b>OIG Special Advisory Bulletin on Exclusion</b>	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. <a href="http://oig.hhs.gov/exclusions/files/sab-05092013.pdf">http://oig.hhs.gov/exclusions/files/sab-05092013.pdf</a>
<b>CMS Compliance Program Policy and Guidance</b>	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. <a href="https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ComplianceProgramPolicyandGuidance">https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ComplianceProgramPolicyandGuidance</a>
<b>Ethics Every Day for Contracted Healthcare Providers and Third Parties</b>	<a href="https://assets.humana.com/is/content/humana/Ethics%20Every%20Day.pdf">https://assets.humana.com/is/content/humana/Ethics%20Every%20Day.pdf</a>
<b>Compliance Program Toolkit</b>	Humana offers an electronic Compliance Toolkit to support healthcare providers and third parties in compliance program enhancement and maturity.  Submit related inquiries to: <a href="mailto:ThirdPartyFDRCompliance@humana.com">ThirdPartyFDRCompliance@humana.com</a>

## 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.

<b>Title XVIII of the Social Security Act</b>	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.  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. <a href="http://www.ssa.gov/OP_Home/ssact/title18/1800.htm">http://www.ssa.gov/OP_Home/ssact/title18/1800.htm</a>
<b>Regulations governing Medicare Parts C and D, and Medicaid, where applicable, found at 42 C.F.R. §§ 422 and 423, respectively</b>	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.  42 C.F.R. § 422.503: <a href="https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-422/subpart-K/section-422.503">https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-422/subpart-K/section-422.503</a>  42 C.F.R. § 422.504: <a href="https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-422/subpart-K/section-422.504">https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-422/subpart-K/section-422.504</a>  42 C.F.R. § 423.504: <a href="https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-423/subpart-K/section-423.504">https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-423/subpart-K/section-423.504</a>
<b>Medicare Managed Care Manual, Chapter 3 – Medicare Marketing Guidelines</b>	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." <a href="https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/FinalPartCMarketingGuidelines.html">https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/FinalPartCMarketingGuidelines.html</a>

## Appendix B: Summary of Applicable Laws and Regulations

<b>Patient Protection and Affordable Care Act (Pub. L. No. 111-148, 124 Stat. 119)</b>	<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"> <li>• Where/how to purchase coverage was expanded</li> <li>• New benefits became available for those eligible for coverage</li> <li>• There were shifts in who is eligible for receiving and retaining coverage and under what arrangements</li> <li>• Organizations offering insurance, like Humana, became subject to greater accountability</li> </ul> <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><a href="http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf">http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf</a></p>
<b>Federal Acquisition Regulation</b>	<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"> <li>• 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</li> <li>• Promotional or marketing materials (e.g., pens, pencils, note pads and calendars) valued at \$15 or less</li> <li>• Tokens of appreciation (e.g., command coins or patches) with a logo, valued at \$15 or less</li> </ul>
<b>Health Insurance Portability and Accountability Act (HIPAA) (Public Law 104-191)</b>	<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><a href="http://aspe.hhs.gov/admnsimp/pl104191.htm">http://aspe.hhs.gov/admnsimp/pl104191.htm</a></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><b>HIPAA Privacy Rule:</b> <a href="http://www.hhs.gov/hipaa/for-professionals/privacy/index.html">http://www.hhs.gov/hipaa/for-professionals/privacy/index.html</a></p> <p><b>HIPAA Security Rule:</b> <a href="http://www.hhs.gov/hipaa/for-professionals/security/index.html">http://www.hhs.gov/hipaa/for-professionals/security/index.html</a></p>
<b>False Claims Acts (31 U.S.C. §§ 3729-3733)</b>	<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><a href="https://www.govinfo.gov/content/pkg/USCODE-2019-title31/pdf/USCODE-2019-title31-subtitleIII-chap37-subchapIII-sec3729.pdf">https://www.govinfo.gov/content/pkg/USCODE-2019-title31/pdf/USCODE-2019-title31-subtitleIII-chap37-subchapIII-sec3729.pdf</a></p> <p><a href="https://www.govinfo.gov/content/pkg/USCODE-2019-title31/pdf/USCODE-2019-title31-subtitleIII-chap37-subchapIII-sec3730.pdf">https://www.govinfo.gov/content/pkg/USCODE-2019-title31/pdf/USCODE-2019-title31-subtitleIII-chap37-subchapIII-sec3730.pdf</a></p> <p><a href="https://www.govinfo.gov/content/pkg/USCODE-2019-title31/pdf/USCODE-2019-title31-subtitleIII-chap37-subchapIII-sec3731.pdf">https://www.govinfo.gov/content/pkg/USCODE-2019-title31/pdf/USCODE-2019-title31-subtitleIII-chap37-subchapIII-sec3731.pdf</a></p> <p><a href="https://www.govinfo.gov/content/pkg/USCODE-2019-title31/pdf/USCODE-2019-title31-subtitleIII-chap37-subchapIII-sec3732.pdf">https://www.govinfo.gov/content/pkg/USCODE-2019-title31/pdf/USCODE-2019-title31-subtitleIII-chap37-subchapIII-sec3732.pdf</a></p> <p><a href="https://www.govinfo.gov/content/pkg/USCODE-2019-title31/pdf/USCODE-2019-title31-subtitleIII-chap37-subchapIII-sec3733.pdf">https://www.govinfo.gov/content/pkg/USCODE-2019-title31/pdf/USCODE-2019-title31-subtitleIII-chap37-subchapIII-sec3733.pdf</a></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"> <li>– Retaliation against individuals for investigating, filing, or participating in a whistle blower action is prohibited.</li> <li>– If the action is successful, the plaintiff is rewarded with a percentage of the recovery.</li> </ul> <p><b>Please note:</b> 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>
<b>Federal Criminal False Claims Statutes (18 U.S.C. §§ 287,1001)</b>	<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"> <li>• Falsifying, concealing, or covering up by any trick, scheme or device, a material fact related to any claim(s) for government payment;</li> <li>• Making any materially false, fictitious, or fraudulent statement or representation; or</li> <li>• Making or using any false writing or document knowing it contains any materially false, fictitious, or fraudulent statement or entry.</li> </ul> <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"> <li>• Made or presented a false, fictitious, or fraudulent claim to a department of the United States;</li> </ul>

	<ul style="list-style-type: none"> <li>Knew the claim was false, fictitious, or fraudulent; and</li> <li>Did so with the specific intent to violate the law or with awareness that what s/he was doing was wrong.</li> </ul> <p><a href="http://www.gpo.gov/fdsys/pkg/USCODE-2011-title18/pdf/USCODE-2011-title18-partI-chap15-sec287.pdf">http://www.gpo.gov/fdsys/pkg/USCODE-2011-title18/pdf/USCODE-2011-title18-partI-chap15-sec287.pdf</a>  <a href="http://www.gpo.gov/fdsys/pkg/USCODE-2011-title18/pdf/USCODE-2011-title18-partI-chap47-sec1001.pdf">http://www.gpo.gov/fdsys/pkg/USCODE-2011-title18/pdf/USCODE-2011-title18-partI-chap47-sec1001.pdf</a></p>
<b>Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b))</b>	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.  <a href="http://www.ssa.gov/OP_Home/ssact/title11/1128B.htm#">http://www.ssa.gov/OP_Home/ssact/title11/1128B.htm#</a>
<b>The Beneficiary Anti-Inducement Statute (42 U.S.C. § 1320a-7a(a)(5))</b>	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.  <a href="https://www.govinfo.gov/content/pkg/USCODE-2019-title42/pdf/USCODE-2019-title42-chap7-subchapXI-partA-sec1320a-7a.pdf">https://www.govinfo.gov/content/pkg/USCODE-2019-title42/pdf/USCODE-2019-title42-chap7-subchapXI-partA-sec1320a-7a.pdf</a>
<b>OIG General Policy Statement Regarding Gifts</b>  (Note: Humana has Medicaid contracts with state agencies that could have different gift policies. Email questions to the Ethics Office at <a href="mailto:ethics@humana.com">ethics@humana.com</a> )	<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"> <li>A gift to a beneficiary as long as the gift has a retail value of \$15 or less</li> <li>Multiple gifts to a beneficiary, 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</li> </ul> <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><a href="https://oig.hhs.gov/fraud/docs/alertsandbulletins/OIG-Policy-Statement-Gifts-of-Nominal-Value.pdf">https://oig.hhs.gov/fraud/docs/alertsandbulletins/OIG-Policy-Statement-Gifts-of-Nominal-Value.pdf</a></p>
<b>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))</b>	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:  <a href="https://www.govinfo.gov/content/pkg/USCODE-2019-title42/pdf/USCODE-2019-title42-chap7-subchapXVIII-partC-sec1395w-27.pdf">https://www.govinfo.gov/content/pkg/USCODE-2019-title42/pdf/USCODE-2019-title42-chap7-subchapXVIII-partC-sec1395w-27.pdf</a>
<b>Foreign Corrupt Practices Act (FCPA)</b>	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.  <a href="https://www.justice.gov/criminal-fraud/foreign-corrupt-practices-act">https://www.justice.gov/criminal-fraud/foreign-corrupt-practices-act</a>
<b>Civil monetary penalties of the Social Security Act (42 U.S.C. § 1395w-27 (g))</b>	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: <ul style="list-style-type: none"> <li>Enrolling an individual in any such plan without the prior consent of the individual or the individual's designee</li> <li>Failing to re-enroll an eligible individual</li> <li>Denying or discouraging an eligible individual from plan enrollment</li> <li>Noncompliance with marketing restrictions surrounding these plans</li> <li>Failing substantially to provide medically necessary items and services that are required (under law or contract) to an individual covered under the contract</li> </ul> <p><a href="https://www.govinfo.gov/content/pkg/USCODE-2019-title42/pdf/USCODE-2019-title42-chap7-subchapXVIII-partC-sec1395w-27.pdf">https://www.govinfo.gov/content/pkg/USCODE-2019-title42/pdf/USCODE-2019-title42-chap7-subchapXVIII-partC-sec1395w-27.pdf</a></p>
<b>Physician Self-referral ("Stark") Statute (42 U.S.C. § 1395nn)</b>	<p>This statute:</p> <ul style="list-style-type: none"> <li>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</li> <li>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</li> </ul> <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:  <a href="https://www.cms.gov/PhysicianSelfReferral/">https://www.cms.gov/PhysicianSelfReferral/</a></p>

<b>Fraud and Abuse, Privacy and Security Provisions of the Health Insurance Portability and Accountability Act, as modified by HITECH Act</b>	<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"> <li>• Use of electronic health records, including incentives for adopting them and requirements around their disclosure</li> <li>• How to secure protected health information appropriately</li> <li>• When and to whom notifications should be made in regard to data breaches of unsecured protected health information (PHI)</li> </ul> <p><a href="http://www.healthit.gov/policy-researchers-implementers/health-it-legislation-and-regulations">http://www.healthit.gov/policy-researchers-implementers/health-it-legislation-and-regulations</a></p>
<b>Fraud Enforcement and Recovery Act of 2009</b>	<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><a href="http://www.gpo.gov/fdsys/pkg/PLAW-111publ21/pdf/PLAW-111publ21.pdf">http://www.gpo.gov/fdsys/pkg/PLAW-111publ21/pdf/PLAW-111publ21.pdf</a></p>
<b>CMS Data Use Agreement</b>	<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><b>Disclosure</b>, 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"> <li>• Any individual's access to the data must only be on a need-to-know basis.</li> <li>• 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.</li> </ul> <p><b>Sufficient Data Safeguards</b> 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><b>Handling of Suspected or Detected Breaches</b></p> <ul style="list-style-type: none"> <li>• This matter is addressed in the Effective Communications section of this policy under "Methods for Reporting Suspected or Detected Noncompliance to Humana."</li> </ul> <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>
<b>All sub-regulatory guidance produced by CMS and HHS, such as manuals, training materials, HPMS memos and guides</b>	<p>Vast guidance resources are available on the following websites:</p> <p>CMS: <a href="https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Guidance.html">https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Guidance.html</a>  <a href="https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions">https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions</a></p> <p>U.S. Department of Health and Human Services:</p> <p><a href="http://www.hhs.gov/">http://www.hhs.gov/</a>  <a href="http://www.hhs.gov/regulations/index.html">http://www.hhs.gov/regulations/index.html</a></p>
<b>Annual review, update and approval deployment of compliance policies and procedures, including the standards of conduct</b>	<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)  <a href="https://www.govinfo.gov/content/pkg/CFR-2020-title42-vol3/pdf/CFR-2020-title42-vol3-sec422-503.pdf">https://www.govinfo.gov/content/pkg/CFR-2020-title42-vol3/pdf/CFR-2020-title42-vol3-sec422-503.pdf</a></p> <p>C.F.R. §§ 423.504(b)(4)(vi)(B)  <a href="https://www.govinfo.gov/content/pkg/CFR-2020-title42-vol3/pdf/CFR-2020-title42-vol3-sec423-504.pdf">https://www.govinfo.gov/content/pkg/CFR-2020-title42-vol3/pdf/CFR-2020-title42-vol3-sec423-504.pdf</a></p>

**Note:** Security and privacy of information must be in accordance with all related federal and state requirements, not just the HIPAA Act and HITECH Act

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