Resources

Appendix A: Resources

Federal Register – Medicare Program; Contract Year 2019 Policy and Technical Changes	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. **https://www.gpo.gov/fdsys/pkg/FR-2018-04-16/pdf/2018-07179.pdf**
OIG Special Advisory Bulletin on Exclusion	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. **http://oig.hhs.gov/exclusions/files/sab-05092013.pdf**
CMS Compliance Program Policy and Guidance	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. **https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ComplianceProgramPolicyandGuidance.html**

Appendix B: Summary of Applicable Laws and Regulations

Title XVIII of the Social Security Act	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. **http://www.ssa.gov/OP_Home/ssact/title18/1800.htm**

Regulations governing Medicare Parts C and D, and Medicaid, where applicable, found at 42 C.F.R. §§ 422 and 423, respectively	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: **https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&rgn=div8&view=text&node=%2042%3A3.0.1.1.9.11.5.4&idno=42** 42 C.F.R. § 422.504: **https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=c41f978c39319dbc1d0a601eba47dee%200&ty=HTML&h=L&r=SECTION&n=se42.3.422_1504** 42 C.F.R. § 423.504: **https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=808d3484cc31371f557c19a256928842&ty=HTML&h=L&r=SECTION&n=42y3.0.1.1.10.11.5.5**
Medicare Managed Care Manual, Chapter 3 – Medicare Marketing Guidelines	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." **https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/FinalPartCMarketingGuidelines.html**
Patient Protection and Affordable Care Act (Pub. L. No. 111-148, 124 Stat. 119)	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: • 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 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. There are other titles that could also impact your organization, although not directly in regard to Humana. The act is available here for review: **http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf**
Federal Acquisition Regulation	This regulation prohibits gifts with greater than $15 fair market value from being given to, or received from, the government. The exceptions are: • 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

Health Insurance Portability and Accountability Act (HIPAA) (Public Law 104-191)	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. **http://aspe.hhs.gov/admnsimp/pl104191.htm** 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. Your organization, as well as Humana, is required to 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. **http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html** **http://www.hhs.gov/ocr/privacy/hipaa/understanding/srsummary.html**
False Claims Acts (31 U.S.C. §§ 3729-3733)	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. **http://www.gpo.gov/fdsys/pkg/USCODE-2011-title31/pdf/USCODE-2011-title31-subtitleIII-chap37- subchapIII-sec3729.pdf** **http://www.gpo.gov/fdsys/pkg/USCODE-2011-title31/pdf/USCODE-2011-title31-subtitleIII-chap37- subchapIII-sec3730.pdf** **http://www.gpo.gov/fdsys/pkg/USCODE-2011-title31/pdf/USCODE-2011-title31-subtitleIII-chap37- subchapIII-sec3731.pdf** **http://www.gpo.gov/fdsys/pkg/USCODE-2011-title31/pdf/USCODE-2011-title31-subtitleIII-chap37- subchapIII-sec3732.pdf** **http://www.gpo.gov/fdsys/pkg/USCODE-2011-title31/pdf/USCODE-2011-title31-subtitleIII-chap37- subchapIII-sec3733.pdf** 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." – 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. **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.

Federal Criminal False Claims Statutes (18 U.S.C. §§ 287,1001)	Section 1001 applies to anyone whose action(s) related to any claim(s) for government payment consist(s) of any of the following: • 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. 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: • 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 • 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-partI-chap15-sec287.pdf** **http://www.gpo.gov/fdsys/pkg/USCODE-2011-title18/pdf/USCODE-2011-title18-partI-chap47-sec1001.pdf**
Anti-Kickback Statute (42 U.S.C. § 1320a-7b(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. **http://www.ssa.gov/OP_Home/ssact/title11/1128B.htm#f**
The Beneficiary Anti-Inducement Statute (42 U.S.C. § 1320a-7a(a)(5))	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. **http://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/pdf/USCODE-2010-title42-chap7-subchapXI-partA-sec1320a-7a.pdf**
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)	*The OIG stated in guidance that there is a "nominal value" exception that allows a person to give: • 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 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. **https://oig.hhs.gov/fraud/docs/alertsandbulletins/OIG-Policy-Statement-Gifts-of-Nominal-Value.pdf**
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)	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: **http://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/pdf/USCODE-2010-title42-chap7-subchapXVIII-partC-sec1395w-27.pdf**

Foreign Corrupt Practices Act (FCPA)	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. **https://www.justice.gov/criminal-fraud/foreign-corrupt-practices-act**
Civil monetary penalties of the Social Security Act (42 U.S.C. § 1395w-27 (g))	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: • 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 **http://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/pdf/USCODE-2010-title42-chap7-subchapXVIII-partC-sec1395w-27.pdf**
Physician Self-referral ("Stark") Statute (42 U.S.C. § 1395nn)	This statute: • 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 *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. Please refer to the following link for a list of the established exceptions and additional information: **https://www.cms.gov/PhysicianSelfReferral/**
Fraud and Abuse, Privacy and Security Provisions of the Health Insurance Portability and Accountability Act, as modified by HITECH Act	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: • 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 made in regard to data breaches of unsecured protected health information (PHI) **http://www.healthit.gov/policy-researchers-implementers/health-it-legislation-and-regulations**
Fraud Enforcement and Recovery Act of 2009	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. **http://www.gpo.gov/fdsys/pkg/PLAW-111publ21/pdf/PLAW-111publ21.pdf**

CMS Data Use Agreement	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. The overarching components of the CMS Data Use Agreement are as follows: **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). • 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. **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. **Handling of Suspected or Detected Breaches** • This matter is addressed in the Effective Communications section of this policy under "Methods for Reporting Suspected or Detected Noncompliance to Humana." 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. It is your responsibility to consult with your legal counsel to determine when/if there are instances that the CMS Data Use Agreement applies to your organization.
All sub-regulatory guidance produced by CMS and HHS, such as manuals, training materials, HPMS memos and guides	Vast guidance resources are available on the following websites: 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** U.S. Department of Health and Human Services: **http://www.hhs.gov/** **http://www.hhs.gov/regulations/index.html**
Annual review, update and approval deployment of compliance policies and procedures, including the standards of conduct	This federal government requirement also applies to organizations and those supporting them in meeting contractual obligations to Humana. **C.F.R. §§ 422.503(b)(4)(vi)(B)** **http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&rgn=div8&view=text&node=42%3A3.0.1.1.9.11.5.4&idno=42** **C.F.R. §§ 423.504(b)(4)(vi)(B)** **https://www.gpo.gov/fdsys/pkg/CFR-2005-title42-vol2/pdf/CFR-2005-title42-vol2-sec423-504.pdf**