

CVS Health Omnicare Corporate Integrity Agreement (“CIA”) Policy

POLICY SUMMARY

CVS Health® (the “Company”) entered into a Corporate Integrity Agreement (“CIA”) with the Office of Inspector General, Department of Health and Human Services (“OIG”) in October 2016 to resolve allegations concerning certain business practices of the Company’s Omnicare® business unit. The CIA requires that CVS Health develop and implement a Policy regarding certain federal healthcare program requirements and make this Policy available to “Covered Persons”, which is a defined term under the CIA, and includes certain colleagues, vendors, subcontractors, customers and other third parties.

This Policy outlines the requirements for Covered Persons as required by the CIA. Specifically, this Policy is designed to ensure that Covered Persons understand the elements of the Anti-Kickback Statute and Stark Law and the obligation to report violations and/or seek guidance when necessary. The Company is committed to complying with all Federal health care program requirements, including but not limited to, the Anti-Kickback Statute and Stark Law.

SCOPE

This Policy applies to certain vendors, subcontractors, customers and other third parties as defined by the CIA. This policy applies to all Omnicare locations, and subsidiaries involved in Institutional Pharmacy Services (“IPS Operations”). Please see the Definitions Section of this Policy for additional information.

POLICY

I. Federal Anti-Kickback Statute (refers to 42 U.S.C. § 1320a-7b (b)):

1. The Federal Anti-Kickback Statute (“AKS”) prohibits payment or receipt of any “Remuneration” intended to induce referrals or the purchasing, leasing or ordering of any item or service that may be reimbursed, in whole or in part, under a Federal Health Care Program, such as Medicare or Medicaid. It also prohibits payment or receipt of any Remuneration intended to induce the recommendation of the purchasing, leasing or ordering of any such item or service.
2. The AKS applies to any item or service that might be paid for by Medicare or any other Federal or state health care program.
3. Examples of potential violations of the AKS: Offering, paying, soliciting or receiving anything of value, directly or indirectly, to or from any potential source or recipient of health care business or referrals could implicate the Anti-Kickback Statute if even one purpose is to generate health care business or referrals.

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“Anything of value” could be in the form of cash, cash equivalents, discounts, forgiveness of debt or other payment obligations, interest-free loans or lines of credit, equipment, services, use of Omnicare property, use of Omnicare personnel, expensive gifts, entertainment, gratuities, business courtesies, promotional items, business opportunities, or anything that benefits the recipient and for which the recipient would otherwise incur a cost to obtain.

4. A violation of the Anti-Kickback Statute can result in criminal and civil penalties. A violation is a felony punishable by a fine of up to \$100,000 per violation and imprisonment for up to 10 years. In addition, civil penalties may be imposed of up to \$102,522 for each violation plus damages of up to three times the total amount of the unlawful remuneration.

Both parties that participate in an impermissible transaction can be subject to criminal and civil penalties and administrative sanctions. Violation of the Anti-Kickback Statute may result in exclusion from participation in Federal health care programs, such as the Medicare and Medicaid programs.

5. If a transaction, relationship, or payment is structured in a manner that meets all of the requirements of a safe harbor, it can be protected from civil or criminal penalty under the Federal Anti-Kickback Statute.

II. Stark Law (refers to 42 USC § 1395nn):

1. The Stark Law prohibits referrals by a physician to an entity for “designated health services” if the physician or an immediate family member of the physician has a “financial relationship” with the entity receiving the referral. The Stark Law further prohibits the entity receiving a prohibited referral from presenting a claim to Medicare or Medicaid for the designated health service furnished under the prohibited referral.
2. The Stark Law is not an intent based statute. Thus, receipt of a referral from a physician where a financial relationship exists results in a violation of the Stark Law, regardless of intent.
3. Under the Stark Law, CVS Health cannot accept referrals for “designated health services” from a physician with whom CVS Health has a “financial relationship.” The “designated health services” covered by the Stark Law include outpatient prescription drugs and home health services.

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4. A “financial relationship” between CVS Health and a physician will be deemed to exist if a physician (or a family member of the physician) holds an ownership or investment interest in CVS Health or is a party to a “compensation relationship” with CVS Health. A “compensation arrangement” is defined broadly to include any arrangement involving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind between a physician (or family member) and an entity. Thus, a “financial relationship” could be created by a consulting agreement with a physician, the sale of product to a physician, or the provision of free goods to a physician.
5. Certain exceptions have been created where relationships with a physician will not be deemed to create a “financial relationship” under the Stark Law. Exceptions include, but are not limited to:
 - a. The “personal services exception” to the Stark Law protects fair market value payments to a physician for legitimate, commercially reasonable and necessary services that are provided pursuant to a services agreement, subject to the satisfaction of certain additional requirements. This exception is relevant to the situation where CVS Health desires to engage a physician to provide consulting services.
 - b. The Stark Law also has an exception for payments made by a physician for items or services if the items or services are furnished at a price that is consistent with fair market value. This exception is relevant to situations where a physician is a purchaser of products from CVS Health.
 - c. Other exceptions to the definition of “financial relationship” may be available for a particular business arrangement. The CVS Health Legal Department will provide guidance on the appropriate structure of relationships between CVS Health and physicians.
6. CVS Health has developed controls for protection against legal risk to the company through this policy, and this policy will be strictly enforced.
7. A violation of the Stark Law may result in exclusion from participation in Medicare and Medicaid programs.

III. Reporting Responsibilities:

All Company Agents are required to report to the Chief Compliance Officer or designee any suspected violations of the Federal Anti-Kickback Statute, Stark Law, or any other law or regulation. Company Agents may use the CVS Health Ethics Line (1-877-CVS-2040) for reporting purposes. As an alternative to calling, reports or questions may be directed to the Ethics Line using this confidential email address: Ethics.BusinessConduct@cvs.com.

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DEFINITIONS

1. **OIG:** The Office of Inspector General for the U.S. Department of Health and Human Services (HHS).
2. **CIA:** The OIG negotiates corporate integrity agreements (CIAs) with health care providers and other entities as part of the settlement of Federal health care program investigations arising under a variety of civil false claims statutes.
3. **“IPS Operations”** means all operations conducted by CVS Health, including, but not limited to, those conducted under the Omnicare and NeighborCare names, relating to institutional pharmacy services, including, but not limited to, the furnishing of pharmacy or patient care items or services to long-term care facilities, mental and behavioral health institutions, developmental disability centers, penal institutions, and government facilities. For purposes of the CIA, IPS Operations does not include the operations conducted by CVS Health’s pharmacy benefit manager, CVS Caremark; CVS Health’s open door retail pharmacies or distribution centers; NovoLogix; Accordant; Coram; CVS Specialty; MinuteClinic; SilverScript; CVS Health’s Trade group; or any prescription drug plans owned by or operated for the benefit of CVS Health.
4. **“Federal health care program”** has the meaning set forth at 42 U.S.C. § 1320a-7b(f), and includes Medicare, Medicaid, Medicare Part D plans, and certain other plans or programs which provide health benefits and are funded directly, in whole or in part, by the Federal government.
5. **“Agent”:** Any Colleague or Contractor.
6. **“Colleague”:** Any full-time, part-time, temporary, or casual employee of CVS Health® and each of its subsidiaries and affiliates, along with paid interns and externs employed by CVS Health® and each of its subsidiaries and affiliates.
7. **“Covered Persons”** is a defined term under the CIA, and includes certain colleagues, vendors, subcontractors, customers and other third parties.
8. **“Contractor”** refers to any person who is not an employee and who provides services to CVS Health pursuant to (a) an independent contractor or consulting agreement between the person and CVS Health, or (b) the person’s employment by a third party, where the third party has an agreement with CVS Health to provide such services to CVS Health.