

Anti-Kickback Statute Policy

Purpose & Application

This Anti-Kickback Statute Policy (“Policy”) requires compliance with the Federal Anti-Kickback Statute¹ (the “Anti-Kickback Statute”) and analogous state laws. In addition, it is designed to ensure that all Company² Employees³ and Contractors⁴ understand:

- the elements of the Anti-Kickback Statute; and
- the obligation to report violations and/or seek guidance, where necessary.

This Policy is applicable to all Company business transactions and practices that could implicate the Anti-Kickback Statute and to all Employees and Contractors engaged in such transactions or practices.

Compliance with the Anti-Kickback Statute

The Company is committed to conducting its business transactions and practices in compliance with the Anti-Kickback Statute and analogous state laws. Employees and Contractors shall comply with the requirements of the Anti-Kickback Statute and these state laws as well as all related Company policies and procedures. This means that Employees and Contractors shall not offer or provide anything of value to Customers⁵ to induce them to purchase, prescribe, dispense, recommend, provide favorable formulary status for a Company product, or arrange for any such activity in violation of the Anti-Kickback Statute or state law.

Employees and Contractors shall report suspected violations of the Anti-Kickback Statute and/or related Company policies and procedures consistent with Teva-Compliance-SOPS-03, Reporting Potential Violations, including to The Teva

¹ 42 U.S.C. §1320a-7b(b), as amended.

² “Company” means all Teva entities conducting business in the United States including, without limitation, Teva Pharmaceuticals USA, Inc.; Teva Neuroscience, Inc.; Teva Parenteral Medicines, Inc.; Teva Respiratory, LLC; Teva Women’s Health, Inc.; Ivax Pharmaceuticals, Inc.; Ivax, LLC; and Barr Laboratories, Inc.

³ “Employees” means to all individuals employed by the Company, as defined by Company policy.

⁴ “Contractors” means to all individuals or entities providing services to the Company under a contractual arrangement.

⁵ “Customers” means any individual or entity to whom or which the Company may market and/or sell its products, including, without limitation, physicians, pharmacists, healthcare institutions/clinics, distributors, managed care organizations, wholesalers, and government entities.

Advantage (877-277-3220). In addition, Employees and Contractors may direct any questions regarding the Anti-Kickback Statute and related Company policies and procedures to their supervisor, the Compliance Department, the Legal Department, or The Teva Advantage.

Failure to comply with this Policy may result in:

- disciplinary action, up to and including termination of employment, for Employees; or
- termination of the contractual arrangement, for Contractors.

Elements of the Anti-Kickback Statute

Prohibited Transactions and Practices

The Anti-Kickback Statute prohibits anyone from knowingly and willingly offering, paying, soliciting, or receiving any remuneration intended to induce:

- The purchase, lease, order, or recommending or arranging for the purchase, lease or order of an item or service that is reimbursed under a Federal Health Care Program;⁶ or
- Referrals for an item or service that is reimbursed under a Federal Health Care Program.

In evaluating whether any particular business transaction or practice violates the Anti-Kickback Statute, the government may consider whether the transaction or practice has the potential to:

- increase costs to a Federal Health Care Program, beneficiaries, or enrollees;
- increase the risk of over-utilization or inappropriate utilization;
- raise patient safety or quality-of-care concerns; or
- interfere with appropriate clinical decision making.

Remuneration and Safe Harbors

Remuneration means anything of value given, directly or indirectly, overtly or covertly, in cash or in kind, to a Customer and includes, but is not limited to:

- cash;

⁶ “Federal Health Care Program” means any plan or program that provides health benefits, through insurance or otherwise, that is funded directly, in whole or in part, by the United States Government (including Medicare and Medicaid but not including the Federal Employee Health Benefits Program), or any state health care program.

- free goods;
- free services; and
- payments for items, services or data at above fair market value.

Because the federal government may construe the Anti-Kickback Statute broadly to prohibit otherwise beneficial business transactions or practices, it created “safe harbors”⁷ to shield certain transactions and practices from prosecution under the statute.

To receive the protection of a safe harbor, a transaction or practice must satisfy each element of a safe harbor. Transactions or practices that do not satisfy all elements of a relevant safe harbor are not necessarily illegal but may be subject to heightened scrutiny.

To the extent possible, Company business transactions and practices should comply with an applicable safe harbor. Employees and Contractors should consult with the Legal and Compliance Departments for advice on satisfying the requirements of a safe harbor.

There are numerous safe harbors, which may apply to any particular transaction or practice. The following safe harbors are particularly relevant to the Company’s business transactions and practices:

- **Discount Safe Harbor**⁸

This safe harbor permits discounts and rebates, which must be given or set at the time of the sale, to Customers that submit claims to Federal Health Care Programs if the discounts and rebates are properly disclosed.

This safe harbor does not protect, and the Company shall not offer, discounts in the form of up-front payments, signing bonuses, or “prebates.”

- **Personal Services Safe Harbor**⁹

This safe harbor permits service arrangements (e.g., consulting arrangements) with Customers, including healthcare professionals, if there is a legitimate need for the service and other conditions are satisfied, including the payment of compensation at fair-market-value rates.

- **Managed Care Safe Harbor**¹⁰

⁷ The Anti-Kickback Statute Safe Harbors, 42 C.F.R. § 1001.952 *et seq.*, as amended.

⁸ 42 C.F.R. §1001.952(h).

⁹ 42 C.F.R. §1001.952(d).

¹⁰ 42 C.F.R. §1001.952(t).

This safe harbor permits the sale of discounted items or services, directly or indirectly, through wholesalers and other entities, to certain eligible managed care organizations under specified circumstances.

- **Group Purchasing Organizations Safe Harbor¹¹**

This safe harbor permits payment of certain fees to group purchasing organizations under certain circumstances.

Intent to Induce

The Anti-Kickback Statute is an intent-based statute. However, the Anti-Kickback Statute may be violated if *one purpose* of the business transaction or practice is to induce referrals or the purchasing, leasing, or ordering of any item or service, or the recommending of or arranging for such activities, even if there are other legitimate purposes for the transaction or practice.

Penalties

The Anti-Kickback Statute is a criminal statute, the violation of which constitutes a felony punishable by:

- a fine of not more than \$25,000 per offense; and/or
- imprisonment for up to five years.

A conviction also will lead to mandatory exclusion from participation in Federal Health Care Programs. The Office of Inspector General (“OIG”), Department of Health and Human Services, also may impose civil monetary penalties of up to \$50,000 for each violation, plus damages of three times the amount of the remuneration.

The Anti-Kickback Statute applies not only to the Company, but also to its Employees, Contractors, and Customers.

¹¹ 42 C.F.R. §1001.952(j).