Special Advisory Bulletin: Application of the Federal Anti-Kickback Statute to Direct-to-Consumer Prescription Drug Sales by Manufacturers to Patients With Federal Health Care Program Coverage

The Trump Administration is launching TrumpRx, a platform to connect patients seeking lower cost prescription drugs with direct-to-consumer (DTC) programs offered by manufacturers and other private companies to cash-paying patients. These DTC programs create opportunities for cash-paying patients to obtain prescription drugs at lower prices than may be available through other avenues. This Special Advisory Bulletin explains when a pharmaceutical manufacturer's offer and sale of lower cost prescription drugs to Federal health care program enrollees through a DTC program is low risk under the Federal anti-kickback statute.

I. Introduction

This Special Advisory Bulletin addresses the application of the Federal anti-kickback statute to a pharmaceutical manufacturer's offer and sale of prescription drugs through a DTC program to cash-paying patients, including Federal health care program enrollees. Patients may elect to purchase prescription drugs through manufacturers' DTC programs—as part of or outside of TrumpRx—because the prescription drugs may be offered at a lower price than through other channels. The Office of Inspector General (OIG) is mindful of the importance of promoting the affordability of and patient access to medically necessary drugs and strongly supports efforts to make medically necessary drugs more affordable, including through pharmaceutical manufacturers' DTC programs that comply with applicable laws and include the program characteristics we suggest in this Bulletin.[1]

With respect to the financial arrangement between the manufacturer and the cash-paying patient who is a Federal health care program enrollee, there is a low risk that a manufacturer would violate the Federal anti-kickback statute provided that: (1) the prescription drug is not billed to a Federal health care program, (2) the sale of the prescription drug is not conditioned on the current or future order or purchase of any other item or service that is or could become billable to a Federal health care program, and (3) the arrangement aligns with the other characteristics listed below.[2]

[1] Because DTC programs have only recently begun to proliferate, it is impossible to predict the ways in which abuse may occur in such programs and how best to minimize the risk of such abuse. Consequently, this Bulletin cannot, and is not intended to, be an exhaustive or definitive discussion of relevant risks of DTC programs. We may amend this Bulletin on a periodic basis as we gain more experience with these programs.

[2] We understand that some pharmaceutical manufacturers may effectuate DTC programs using a buy-down coupon to the dispensing pharmacy. While this Bulletin does not speak to any remuneration the manufacturer offers or pays to a pharmacy, when the pharmacy coupon passes through to the Federal health program enrollee—effectuating enrollees' cash purchase of lower cost drugs—it presents a low risk when the arrangement aligns with the characteristics described here.

Importantly, because the Federal anti-kickback statute is a criminal statute, any determination as to whether a particular arrangement violates the statute can be made only through a case-by-case assessment of all relevant facts and circumstances, including the intent of the parties.

This Bulletin addresses only the DTC sales transaction between the manufacturer and the cash-paying patient.[3] It does not address the application of the Federal anti-kickback statute to any arrangements that the manufacturer may have with physicians, pharmacies, pharmacy benefit managers, telemedicine vendors, marketers, or other individuals or entities. It also does not address any arrangements that those individuals or entities may have among themselves or with Federal health care program enrollees. OIG will issue separately a request for information to seek public feedback with respect to rulemaking or guidance, if any, that may be needed regarding the application of certain fraud and abuse laws to such arrangements as they relate to DTC sales. This Bulletin does not address DTC sales to uninsured individuals or individuals insured solely by commercial health plans because, as a general matter, the Federal anti-kickback statute does not apply to such sales.

II. Overview of the Federal Anti-Kickback Statute

The Federal anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce, or in return for, the referral of an individual to a person for the furnishing of, or arranging for the furnishing of, any item or service reimbursable under a Federal health care program.[4] The statute's prohibition also extends to remuneration to induce, or in return for, the purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any good, facility, service, or item reimbursable by a Federal health care program.[5] For purposes of the Federal anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement in which one purpose of the remuneration is to induce referrals for items or services reimbursable by a Federal health care program.[6] Violation of the statute constitutes a felony punishable by a maximum fine of $100,000, imprisonment up to 10 years, or both. Conviction also will lead to exclusion from Federal health care programs, including Medicare and Medicaid. When a person commits an act described in section 1128B(b) of the Social Security Act (the Act), OIG may initiate administrative proceedings to impose civil monetary penalties on such person under section 1128A(a)(7) of the Act. OIG also

[3] As such, this Bulletin does not address the civil monetary penalty provision prohibiting inducements to beneficiaries because the provision does not apply to arrangements between pharmaceutical manufacturers and beneficiaries.

[4] Section 1128B(b) of the Social Security Act (the Act).

[5] *Id.*

[6] *E.g., United States v. Nagelvoort*, 856 F.3d 1117 (7th Cir. 2017); *United States v. McClatchey*, 217 F.3d 823 (10th Cir. 2000); *United States v. Davis*, 132 F.3d 1092 (5th Cir. 1998); *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989); *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985).

may initiate administrative proceedings to exclude such person from Federal health care programs under section 1128(b)(7) of the Act.

III. Application of the Federal Anti-Kickback Statute to DTC Prescription Drug Sales by Manufacturers to Patients With Federal Health Care Program Coverage

We have identified two primary ways that pharmaceutical manufacturers' DTC sales to Federal health care program enrollees could be problematic under the Federal anti-kickback statute. First, the manufacturer might offer the Federal health care program enrollee a prescription drug at a lower cost than otherwise may be available to the enrollee as a marketing tool to induce the enrollee to purchase other prescription drugs, items, or services manufactured or offered by that pharmaceutical manufacturer for which payment may be made, in whole or in part, by a Federal health care program. Second, the manufacturer might use the DTC program to influence enrollees to take that pharmaceutical manufacturer's drug with an expectation that the enrollee's Federal health care program might be billed for the drug in the future (e.g., if the drug becomes more affordable through the enrollee's Federal health care program coverage), sometimes known as a seeding program.

When the offer and sale of a prescription drug by a manufacturer to a Federal health care program enrollee align with the characteristics below, there is a low risk that a manufacturer would violate the Federal anti-kickback statute. In particular, the following characteristics minimize the risk of fraud and abuse under the Federal anti-kickback statute presented by a manufacturer's DTC prescription drug offer and sale to a Federal health care program enrollee:

- The individual has a valid prescription from an independent, third-party prescriber.
- When an individual purchases prescription drugs through a pharmaceutical manufacturer's DTC program, no claims for these drugs are submitted to any insurer, including any Federal health care program. This means that individuals obtain the drugs without using their Medicare outpatient prescription drug benefit or any other Federal health care program benefit. As such, the DTC program price that a Medicare Part D enrollee pays does not count toward their Medicare Part D true-out-of-pocket or total Medicare Part D spending for any purpose.
- The pharmaceutical manufacturer does not use the DTC program for one product as a vehicle to market other federally reimbursable products it manufactures or services it provides.
- The pharmaceutical manufacturer does not condition the DTC program price for any drugs offered through its DTC program on any future purchases (of that drug or any other items or services).
- The pharmaceutical manufacturer makes the prescription drug available to the Federal health care program enrollee through its DTC program for at least one full plan year.
- The prescription drugs offered by the pharmaceutical manufacturer through the DTC program do not include controlled substances.[7]

[7] We will continue to evaluate whether the provision of other types of drugs through DTC programs may present a risk of inappropriate utilization.

To protect patient safety and reduce the risk of contraindicated or duplicative prescriptions, it also would be prudent for manufacturers operating DTC programs to establish mechanisms to communicate with the Federal health care program enrollee's plan (e.g., Medicare Part D, Medicare Advantage, Medicaid) to facilitate appropriate drug utilization review and medication therapy management by insurers.

When pharmaceutical manufacturers offer and sell DTC prescription drugs consistent with the characteristics in this Bulletin, we believe that the benefits of lower cost drugs outweigh the risks under the Federal anti-kickback statute, absent unforeseen circumstances. Additionally, because Federal health care programs are not billed for the drugs purchased through a pharmaceutical manufacturers' DTC program, without further information to the contrary we are not concerned about inappropriately increased costs to Federal health care programs through the provision of these particular drugs to enrollees.

As noted above, this Bulletin does not address any other arrangements or remuneration relating to the provision of drugs offered and provided through a DTC program beyond the DTC program price offered and provided by the pharmaceutical manufacturer to the purchasing individual. The advisory opinion process[8] and OIG's frequently asked questions process[9] remain available if parties seek OIG's assessment of these other types of arrangements under the Federal anti-kickback statute or other OIG administrative enforcement authorities.[10]

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[8] Office of Inspector General, "Advisory Opinion Process." Accessed on Dec. 29, 2025.

[9] For additional information on OIG's frequently asked questions process, see Office of Inspector General, "Frequently Asked Questions." Accessed on Dec. 29, 2025.

[10] In addition, protection through certain existing safe harbors (e.g., the personal services and management contracts and outcomes-based payment arrangements safe harbor at 42 C.F.R. § 1001.952(d)) would be available for such arrangements, provided all conditions of the applicable safe harbor are satisfied.