

## SELLING PRESCRIPTION DRUGS DIRECTLY TO PATIENTS? OIG FLAGS ANTI-KICKBACK PITFALLS WITH TRUMPRX AND OTHER DTC PROGRAMS

On January 27, 2026, the U.S. Department of Health and Human Services (“HHS”) Office of the Inspector General (“OIG”) issued a [Special Advisory Bulletin](#) (the “Bulletin”) detailing how the federal Anti-Kickback Statute (“AKS”) applies to direct-to-consumer (“DTC”) prescription drug sales by manufacturers to cash-paying patients enrolled in federal health care programs. The Bulletin provides a roadmap to structure DTC prescription drug programs in a low-risk manner under the AKS.

### BACKGROUND

The AKS imposes criminal sanctions for individuals and entities that knowingly and willfully offer, pay, solicit or receive remuneration to induce or reward referrals or the generation of federal health care program business. The statute has several “safe harbors” that allow certain remuneration that would otherwise violate the AKS.

TrumpRx is an online platform that recently went “live.” The platform’s objective is to reduce the costs of prescription drugs for patients by connecting them with DTC programs offered by pharmaceutical manufacturers and other private companies.

As it is currently written, the AKS does not have a safe harbor designed for these DTC programs. Therefore, there is a risk that the lower prices offered by manufacturers through these DTC programs to patients who are federal health care program beneficiaries could be viewed as an impermissible inducement for federal health care program business (i.e., other drugs offered by the manufacturer that *are* paid for by federal health programs).

### SPECIFICS OF THE OIG SPECIAL ADVISORY BULLETIN

The Bulletin applies to all pharmaceutical DTC programs, including those that are not a part of the TrumpRx platform. However, the Bulletin only applies to cash-paying patients. Importantly, the Bulletin does not apply to arrangements between manufacturers and physicians, pharmacies, pharmacy benefit managers, telemedicine vendors or other individuals or entities. The OIG noted that it will issue a separate request for information to seek public feedback on such arrangements as they relate to DTC sales.

The Bulletin establishes two potential conflicts between DTC programs’ relationship with patients and the AKS:

1. The manufacturer may offer the patient a lower cost on a prescription drug in order to induce the patient to purchase other drugs offered by the manufacturer for which a federal health care program pays; or
2. The manufacturer may use the DTC program as a “seeding program,” whereby cash-paying patients are offered a reduced price on a drug to induce them to continue using that same drug in future instances where reimbursement is made by a federal health care program.

To mitigate these concerns, the OIG specifies characteristics that make an arrangement between a manufacturer and a patient enrolled in a federal health care program low risk for AKS purposes:

- The individual has a valid prescription from an independent, third-party prescriber.
- When an individual purchases drugs through a DTC program, no claims are submitted to any insurer, including a federal health care program.
- The 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 manufacturer does not condition the DTC program price for drugs on any future purchases.
- The 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 drugs offered by the manufacturer through the DTC program are not controlled substances.

## **PRACTICAL TAKEAWAYS**

- Manufacturers who adopt the criteria outlined in the Bulletin can limit AKS risk associated with DTC programs, even in the absence of a DTC safe harbor.
- The OIG also recommends that manufacturers operating DTC programs establish mechanisms to communicate with the federal health care program enrollee's plan (e.g., Medicare Part D, Medicare Advantage, Medicaid) to facilitate drug utilization review and medication therapy management.

If you have any questions or would like additional information on these topics, please contact:

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