



## OIG Special Advisory Bulletin Addresses Direct-to-Consumer Prescription Drug Sales and Provides a Framework for Compliant Programs

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On January 27, 2026, the U.S. Department of Health and Human Services Office of Inspector General (the **OIG**) issued a Special Advisory Bulletin (the **Bulletin**) addressing the application of the federal anti-kickback statute (the **AKS**) to direct-to-consumer (**DTC**) prescription drug sales.

The Bulletin, the OIG's first Special Advisory Bulletin since September 2014, was issued in response to the proliferation of DTC programs. The Bulletin, which sets forth the framework under which a manufacturer's DTC program presents a low risk of violating the AKS, is viewed by the growing DTC industry as favorable guidance. DTC programs offering modern weight-loss medications, such as GLP-1 drugs, are becoming increasingly popular, and the Bulletin provides a helpful framework to support the viability of these programs.

### **AKS RISKS ASSOCIATED WITH DTC PRESCRIPTION DRUG SALES**

The AKS makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward patient referrals or the generation of business for services payable by federal healthcare programs such as Medicare and Medicaid. Each AKS violation is a felony punishable by a maximum fine of \$100,000, imprisonment for up to 10 years, or both. Each AKS violation may also carry additional civil monetary penalties of up to \$50,000, plus treble damages. An AKS violation can also serve as a predicate for liability under the False Claims Act and/or lead to exclusion from federal healthcare programs.

The Bulletin identifies two primary AKS risks associated with pharmaceutical manufacturers' DTC prescription drug sales to federal healthcare program enrollees. First, a manufacturer may offer an enrollee a prescription drug at a low cost to induce the enrollee to purchase other drugs, items, or services offered by the manufacturer for which payment may be made by a federal healthcare program. Second, a manufacturer may use a DTC program to induce an enrollee to take the manufacturer's drug in the hope that the enrollee's federal healthcare program will be billed for the drug in the future. The Bulletin makes clear that it applies only to DTC sales transactions between a pharmaceutical manufacturer and a cash-paying patient. Importantly, the Bulletin confirms that DTC sales to uninsured individuals or individuals insured solely by commercial health plans do not, as a general matter, implicate the AKS.

### **CHARACTERISTICS OF LOW-RISK DTC PROGRAMS**

According to the Bulletin, a DTC program (including a DTC program that dispenses pharmaceuticals to enrollees) with the following characteristics is at low risk of violating the federal AKS:

- The patient has a valid prescription from an independent, third-party prescriber.
- The patient pays for the drug without submitting a claim for the drug to an insurer, including any federal healthcare program.
- The manufacturer does not use the DTC program to market other federally reimbursable products or services.
- The manufacturer does not condition the drug price on any future patient purchases.
- The manufacturer makes the drug available to the patient through the DTC program for at least one full plan year.
- The drugs offered by the manufacturer through the DTC program do not include controlled substances.

The Bulletin also recommends that manufacturers establish open lines of communication with patients' federal healthcare programs to facilitate drug utilization review and medication therapy management.

## **ANALYTICAL CONSTRAINTS**

Though the OIG *generally* considers a DTC program that aligns with the above characteristics to be “low risk,” any determination as to whether a particular DTC program violates the AKS can be made only through a case-by-case assessment of all relevant facts and circumstances, including the parties' intent. DTC programs may not be able to satisfy all of the above characteristics in every circumstance. For example, a DTC program may have a relationship with physician prescribers who receive patient referrals from the DTC program and who ultimately write prescriptions for the drugs after a telehealth encounter.

Moreover, the Bulletin addresses only DTC programs that involve sales between manufacturers and cash-paying patients. It does not, for example, address the application of the AKS to manufacturer arrangements with other individuals or entities, such as providers, pharmacies, vendors, or marketers.

While the Bulletin addresses certain AKS risks related to DTC programs, such programs will still need to navigate other regulatory issues, including corporate practice considerations, licensure and advertising rules, and potential AKS risks related to relationships with other healthcare providers. The OIG reserved the right to amend the Bulletin periodically to address new developments in the DTC space.

## **CONCLUSION**

Underwriters or investors conducting due diligence on companies with DTC programs should assess alignment with the Bulletin's framework as part of their regulatory diligence. Public companies operating DTC programs should also evaluate whether their SEC risk factor disclosures adequately address AKS compliance in light of the OIG's guidance. For more information on structuring or evaluating a DTC program in accordance with the AKS and other healthcare regulatory considerations, please reach out to Banee Pachuca (Partner, Houston), Eric Johnson (Partner, Houston), Ryan Greenberg (Associate, Houston), or your Winston & Strawn relationship attorney.

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