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Healthcare Alert

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OIG issues new guidance on Anti-Kickback Compliance for DTC prescription drug programs

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OIG Bulletin provides guidance on when cash-pay, direct-to-consumer drug programs may be low-risk under the Anti-Kickback Statute.

What's the impact?

- Pharmaceutical manufacturers now have clearer guidance on structuring DTC drug sales without triggering anti-kickback concerns, provided certain conditions are met.
- OIG's Bulletin is limited in scope—only addressing DTC programs between manufacturers and cash-paying patients enrolled in federal health care programs (FHCP). Most DTC programs involve several other parties such as telehealth companies, pharmacies, and prescribers.
- OIG issued a request for information (RFI) seeking public input on whether additional guidance or rulemaking is needed for certain arrangements connected to DTC sales.

On January 27, 2026, the HHS OIG released a Special Advisory Bulletin titled, "Application of the Federal Anti-Kickback Statute (AKS) to Direct-to-Consumer (DTC) Prescription Drug Sales by Manufacturers to Patients with Federal Health Care Program Coverage" (the Bulletin). The Bulletin addresses the application of the federal AKS to pharmaceutical manufacturers' DTC prescription drug sales to cash-paying patients who are also enrolled in FHCPs such as Medicare or Medicaid. This guidance was issued in connection with the Trump administration's launch of TrumpRx, a platform designed to connect patients seeking lower-cost prescription drugs with DTC programs offered by manufacturers and other private companies.

The federal AKS makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce referrals for items or services reimbursable under a FHCP. Violations constitute a felony punishable by fines up to $100,000, imprisonment up to ten years, or both, and can result in exclusion from FHCPs. OIG may also pursue civil monetary penalties under the statute. While the AKS is primarily a criminal statute, violations can lead to liability under the False Claims Act, which imposes treble damages and civil monetary penalties for each violation.

OIG's low-risk framework

The Bulletin identifies two primary concerns with manufacturers' DTC sales to FHCP enrollees: (1) manufacturers could use discounted drug sales as a marketing tool to induce enrollees to purchase other federally reimbursable products; and (2) manufacturers could use DTC programs as "seeding programs" to influence enrollees to use a manufacturer's drug with the expectation that the FHCP will eventually be billed for the drug.

To address these concerns, OIG has outlined characteristics that, when present, indicate a low risk of AKS violations. Specifically, a DTC program would be considered low risk if:

- The individual has a valid prescription from an independent, third-party prescriber.
- No claims for these drugs are submitted to an insurer, including a FHCP.
- The pharmaceutical manufacturer does not use the offer or sale of the drug to market other FHCP reimbursable drugs it provides and does not condition the DTC program price on any future purchases.
- The drug is available through the DTC program for at least one year.
- Drugs offered through the DTC program are not controlled substances.

OIG also recommends that pharmaceutical manufacturers operating DTC programs establish mechanisms to communicate with FHCP enrollees to facilitate appropriate drug utilization review and medication therapy management by insurers.

Limitations of OIG's DTC Guidance for Manufacturers

Importantly, the Bulletin addresses only the DTC sales transactions between the pharmaceutical manufacturer and cash-paying patients, including those enrolled in an FHCP. It does not address how AKS might apply to any arrangement manufacturers have with physicians, pharmacies, pharmacy benefit managers (PBM), telemedicine vendors, marketers, or other prescribed individuals or entities involved in DTC programs. OIG has issued an RFI seeking public feedback on whether additional guidance or rulemaking is needed for other types of arrangements in the industry.

The Bulletin also does not address DTC sales to uninsured individuals or individuals insured solely by commercial health plans, as the federal AKS generally does not apply to such sales. Additionally, OIG notes that because DTC programs have only recently begun to increase, it is impossible to predict all potential fraud and abuse scenarios, and OIG may amend the Bulletin periodically as it gains more experience with these programs.

Anti-Kickback Statute Considerations for DTC Programs

This guidance comes at a time of increasing scrutiny of pharmaceutical manufacturers' DTC practices. As DTC programs encourage patients to purchase medications directly from manufacturers or manufacturer-contracted pharmacies rather than through traditional pharmacy channels, they may also drive increased use of DTC telehealth platforms. In 2025, Senators Durbin, Sanders, Warren, and Welch released an investigative report examining pharmaceutical manufacturers' emerging DTC telehealth platforms, raising concerns about the close relationships between drug manufacturers, prescribers, and telehealth providers; the quality of care delivered through these platforms; and the potential for inappropriate prescriber practices. While the Bulletin provides more clarity on how to structure DTC programs for cash-paying patients, it does not address arrangements between manufacturers and telehealth providers that were the focus of the Senate report.

Pharmaceutical manufacturers considering or currently operating DTC programs should carefully review their program structures against the characteristics outlined in the Bulletin. Programs that comply with these characteristics and avoid billing FHCPs for DTC sales will generally be considered low risk from an AKS perspective. However, manufacturers should remain mindful that any determination as to whether a particular arrangement violates AKS can only be made through a case-by-case assessment of all relevant facts and circumstances, including the intent of the parties. Additionally, the related and broader arrangements with prescribers, pharmacies, PBMs, and other partners involved in DTC programs must be independently reviewed for compliance with AKS, as these arrangements fall outside the scope of the Bulletin and may present separate enforcement risks.

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