HHS-OIG Issues Guidance on Pharma DTC Prescription Drug Sales, but Key Legal Questions Remain

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On January 27, 2026, the U.S. Department of Health and Human Services Office of Inspector General ("OIG") issued a Special Advisory Bulletin titled "*Application of the Federal Anti-Kickback Statute to Direct-to-Consumer Prescription Drug Sales by Manufacturers to Patients with Federal Health Care Program Coverage*."[1] The Special Advisory Bulletin addresses application of the federal Anti-Kickback Statute ("AKS") to a pharmaceutical manufacturer's offer and sale of prescription drugs through a Direct-to-Consumer ("DTC") program to cash-paying patients, including federal health care program beneficiaries. OIG also requests information on whether new regulatory safe harbors could help alleviate the industry's concerns about the legal complications of DTC drug sales.[2]

The Trump Administration is clearly signaling that it is open to working with pharmaceutical manufacturers to find paths toward making DTC programs more widely available. The Administration remains intensely focused on finding ways to lower the cost of prescription drugs and launching TrumpRX, a platform through which Americans will buy drugs directly from pharmaceutical manufacturers at discounted prices. Despite these efforts and OIG's apparent attempt to coax industry into standing up these programs, there remain many open legal questions, including key fraud and abuse questions and a host of related regulatory considerations and complications.

Application of the AKS to DTC Prescription Drug Sales

The Special Advisory Bulletin identifies two primary ways a pharmaceutical manufacturer's DTC program could implicate the AKS. It then provides several

guardrails to protect against the identified risks.

The risk areas identified include:

1. Offering federal health care program beneficiaries prescription drugs at lower costs to market or otherwise inducing the beneficiary to purchase other reimbursable items or services manufactured or offered by the manufacturer for which payment may be made, in whole or in part, by federal health care programs.
2. Influencing beneficiaries to take a prescription drug with the expectation that the beneficiary's federal health care program might be billed for the prescription drug in the future (i.e., using the DTC program as a seeding tool).

To mitigate these risks, OIG recommends that manufacturers adopt six guardrails:

1. Beneficiaries must have a valid prescription from an independent, third-party prescriber.
2. No claims for the drugs purchased through the DTC programs may be submitted to any insurer, including any federal health care programs, and any patient costs for drugs purchased through DTC programs will not apply to beneficiaries' Medicare Part D true-out-of-pocket costs.
3. The prescription drug available through the DTC program must be available to the federal health care beneficiary for at least one full plan year.
4. A manufacturer should not use the DTC program to market other federally reimbursable items or services.
5. A manufacturer should not condition the DTC program price on any future purchases (of that drug or any other item or service).
6. DTC sales programs should not be used for controlled substances.

In addition to these guardrails, the Special Advisory Bulletin recommends that manufacturers develop mechanisms to communicate with federal health care program beneficiaries' plans (e.g., Medicare Part D PDPs) to facilitate appropriate drug utilization review and medication therapy management. This could potentially impose significant costs on the regulated industry, which, in good faith, tries to implement this mechanism that OIG describes as "prudent."

The Special Advisory Bulletin Does Not Address Key Legal Risks, including Critical Fraud and Abuse Questions

The Special Advisory Bulletin narrowly defines its scope to the DTC transaction between the manufacturer and the cash-paying patient. In doing so, the Special Advisory Bulletin does not address many of the operational elements of implementing a DTC program that may implicate the AKS or other fraud and abuse laws, such as the Beneficiary Inducement Statute ("BIS") within the Civil Monetary Penalty Statute – not to mention other laws not within OIG's purview.

Key additional areas/risks in standing up these programs include:

- **Arrangements with third-party telehealth providers and pharmacies, among others.** The Special Advisory Bulletin states that it does not opine on potential AKS risks associated with arrangements with third parties, including physicians, pharmacies, pharmacy benefit managers, telemedicine vendors, and marketers. Relationships with any of these entities would need to be considered separately from the Special Advisory Bulletin. For example, arrangements with telehealth providers who might write a prescription that could be fulfilled through a DTC program are not covered by the Special Advisory Bulletin. Additionally, arrangements between manufacturers and dispensing pharmacies are also not addressed.
- **State licensure issues.** A manufacturer will commonly need to work with third parties to effectuate DTC sales programs

because state medical practice and pharmacy licensure requirements generally restrict who may dispense prescription drugs to patients directly. Thus, a DTC program often will not be limited to just a transaction between the manufacturer and patient. State laws also impact where and how dispensing services are provided (e.g., whether the "sale" transaction is part of the definition of dispensing; whether a non-resident pharmacist must be licensed in each shipment destination state; when and how product substitution may occur).

- **Beneficiary inducements.** The Special Advisory Bulletin noted that it does not consider the BIS because a manufacturer is not a provider under the BIS; thus, the BIS does not directly prohibit providing remuneration to patients (e.g., a lower drug cost) to select a pharmaceutical product. While the lower drug prices offered through the DTC program might not implicate the BIS, other components of a DTC program could implicate the law if the arrangement directs beneficiaries to certain providers (e.g., telehealth providers) or certain pharmacies. For example, a pharmaceutical manufacturer can, in fact, implicate the BIS prohibition if it would provide remuneration to beneficiaries that the manufacturer knows or should know would induce beneficiaries to choose a particular telehealth provider or pharmacy.
- **Implications for government pricing requirements and related rebate liability.** The Special Advisory Bulletin does not address potential implications for government pricing requirements, including under the Medicaid Drug Rebate Program and the Average Sales Price regime. "Direct sales to patients" are excluded from Best Price, AMP, and ASP, but neither CMS guidance nor this Bulletin describe in detail the kind of arrangements that would satisfy the terms of that exclusion.
- **FDA advertising and promotion regulations and requirements.** DTC programs can also raise advertising and promotion issues under the FDA regulatory regime. Consideration should be given to ensure that a DTC program complies with those obligations, including, for example, avoiding any appearance of targeting patients who may not be on-label for the drug. Further, as a general matter, all traditional FDA and FTC ad promo regulations and guidelines will apply to a DTC program.

Notice for Comments

Recognizing the limitations of the Special Advisory Bulletin, OIG issued a request for information in the *Federal Register* seeking input from the public on whether any additions or modifications are needed to the safe harbor regulations under the AKS or the exceptions to the BIS for DTC programs to be established by pharmaceutical manufacturers.[3] OIG is asking for comments on:

- Arrangements that the industry is interested in pursuing in connection with prescription drug DTC programs, how such programs can promote access to and affordability of prescription drugs, and how they can prevent potential harms, such as increased costs, inappropriate steering, unfair competition, inappropriate utilization, poor quality of care, and distorted decision making.
- Suggestions on whether there is a need for new or modified AKS safe harbors or other regulations to address DTC programs; if there is a need, suggestions as to what regulatory changes are needed and why.
- Comments on whether OIG can clarify its positions around DTC programs through mechanisms other than regulations (such as additional guidance like the Special Advisory Bulletin) or whether OIG's current guidance is sufficient to address concerns related to DTC programs.

In addition to the listed topics, manufacturers might address "guidance" in the Special Advisory Bulletin that is not directly related to the AKS and may impose expectations and costs on manufacturers operating DTC programs. For example, OIG's statement that it would be "prudent" for manufacturers operating DTC programs to establish mechanisms to communicate with federal health care program enrollees' plans (e.g., Medicare Part D, Medicare Advantage, Medicaid) to facilitate appropriate drug utilization review and medication therapy management by insurers.

Comments were due March 30, 2026. This comment period provides the life sciences industry an opportunity to seek clarification around key issues currently not addressed in the Special Advisory Bulletin and to shape how these programs can be implemented.

Endnotes

1. OIG, 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 (Jan. 27, 2026), available at *https://oig.hhs.gov/documents/special-advisory-bulletins/11450/OIG--FINAL--Special-Advisory-Bulletin.pdf.*
2. HHS Press Release, HHS Clears Path for Lower-Cost Prescription Drugs Through Direct-to-Consumer Programs (Jan. 27, 2026), available at *https://www.hhs.gov/press-room/oig-clears-path-for-lower-cost-prescription-drugs.html*.
3. 91 Fed. Reg. 3857, 3857-60 (Jan. 29, 2026).

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