Assessing Compliance Risks Around TrumpRx Participation

By **Dominick DiSabatino, Scott Liebman and Julian Klein** (February 12, 2026)

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The genesis of the first direct-to-consumer drug concept in the U.S. is debated.

Going back to at least 2011,[1] Pfizer Inc.'s unorthodox Diplomat Specialty Pharmacy partnership aimed to launch Lipitor DTC in the face of generic competition.

To be sure, there, the strategy did not — nor could it — resemble the more typical DTC format that Pfizer and just about every other large brand in the space offers today.

DTC programs today rely heavily on telehealth, which since the pandemic, has greased the consumer access skids, generating significant U.S. Department of Justice activity[2] and creating reams of work for legal and compliance teams to sort through design and strategy.

And now this system has been further institutionalized by the U.S. government: TrumpRx went live on Feb. 5, positioning the federal government not only as a regulator but also as a facilitator of DTC programs.[3]

TrumpRx at this time is essentially a reproduction of other popular drug coupon websites, but that may very well change in the future to serve as a passthrough to pharma DTC programs, or even to become a DTC program itself. The American consumer nevertheless will ultimately decide whether this endeavor becomes a cornerstone of the healthcare industry.

The first official step in this process came from the U.S. Department of Health and Human Services' Office of Inspector General issuing a special advisory bulletin regarding the application of the federal Anti-Kickback Statute to DTC prescription drug sales.[4]

While the special advisory bulletin allegedly clears the path for the administration's TrumpRx platform and provides assurances to the various companies that plan to

participate in it,[5] both the special advisory bulletin and the accompanying press release make bold statements and introduce a few novel compliance obligations that should be considered when moving these DTC programs forward.

Perhaps unexpectedly, Democratic Sens. Dick Durbin of Illinois, Peter Welch of Vermont and Elizabeth Warren of Massachusetts have voiced concerns, specifically about the potential conflicts of interest and fraud risks related to arrangements with pharmacies and telehealth companies required to get a DTC program off the ground.[6]

This signals broader potential political opposition to the TrumpRx platform or any future rebrand of the same. A later administration could always just cancel the platform and leave it to the free market to handle, but putting the genie back into the bottle at this point is impossible.

The American consumer has spoken, and companies now building these operations should be prepared for more aggressive investigations into telehealth relationships between pharmaceutical companies and the pharmacies involved — regardless of what this or future administrations say or do not say about the merits of DTC platforms.

Key Compliance Pillars of the OIG Bulletin

Briefly, the special advisory bulletin focuses on the sale of prescription drugs directly to cash-paying patients, including those enrolled in federal healthcare programs. The OIG considers these arrangements low-risk under AKS only if certain criteria are met, and outlines six main features to consider.

First, the patient must have a valid prescription issued by an independent third-party prescriber to ensure that there's no improper influence over prescribing decisions.

Second, no claims for these drugs can be submitted to Medicare, Medicaid or any insurer, and such purchases do not count toward the patient's true out-of-pocket costs or total Medicare Part D spending.

Third, the DTC platform cannot serve as a vehicle to market other federally reimbursable products.

Fourth, manufacturers may not condition the DTC price on any future purchases, which serves to ensure price neutrality and avoids inducement concerns.

Fifth, the drug must also remain available at the DTC price for at least one full plan year.

Finally, the program must exclude controlled substances.

The OIG's concerns clearly fall under two theories of harm. The first is the potential for DTC programs to serve as a marketing tool to encourage the purchase of other federally reimbursable products.

The second focuses on the more traditional seeding arrangements, where an enrollee may be enticed to start using a product with the hope that future doses or treatments will ultimately be billed to a federal healthcare program, especially as the patient's disease and therapeutic needs evolve.

Key Critiques

Just two days after OIG issued the special advisory bulletin, Sens. Durbin, Welch and Warren sent a letter to the inspector general raising concerns about the guidance, particularly in the context of the TrumpRx launch.

Telehealth arrangements continue to be a significant concern for this group of senators. In the past, this crew — along with Sen. Bernie Sanders, I-Vt. — wrote letters to telehealth companies regarding their financial relationships with large pharmaceutical manufacturers, as well as to the pharmaceutical companies themselves.[7]

Further, in July 2025, they released an investigatory report on telehealth platforms servicing these arrangements.[8] Previously, in 2024, Sens. Durbin and Mike Braun, R-Ind., had **proposed a crackdown** on online drug advertising in the age of social media and telehealth.

In the recent letter, the senators highlight several pressure points likely to attract future investigations.

Telehealth Independence

While OIG requires an independent, third-party prescriber, the Durbin letter points to past investigations where drug manufacturers partnered with telehealth companies that routed patients to specific high-cost medications via cursory virtual visits.

The senators reference findings that, in some cases, patients referred to certain telehealth providers had a 100% prescription rate for the manufacturer's drug, raising doubts about true prescriber independence.

Therefore, manufacturers should be prepared for OIG and Congress to look past the independent label. If a telehealth provider has a 100% prescription rate for a specific manufacturer's drug, OIG may determine the prescriber is not truly independent.

Seeding Issues

The Durbin letter emphasizes the seeding risk in GLP-1 medications, particularly where manufacturers offer discounted initial doses on DTC platforms, but require patients to later titrate to higher, more expensive doses that could be billed to a federal healthcare program.

Conflicts and Steering

The letter highlights potential conflicts of interest, specifically mentioning BlinkRx and its board membership by Donald Trump Jr. This suggests that so-called steering — whether through the TrumpRx interface or through manufacturer partnerships — will be scrutinized as a potential form of remuneration to induce referrals, even if the initial transaction is cash-pay.

DTC Advertising

Another area of concern cited in the Durbin letter is DTC advertising, particularly whether manufacturers touting participation in TrumpRx must adhere to the guidance and include clear disclosures regarding insurance coverage, pricing and the necessity of a valid independent prescription.

Implementation Friction and Risk Forecasting

Perhaps the most restrictive element of the special advisory bulletin is the requirement that the DTC price remain available for at least one full plan year. This is designed, as described by OIG, specifically to combat DTC-hopping, or so-called bait-and-switch tactics.

Of course, this introduces a financial and operational commitment to the design of these

DTC programs that affects the economics of the decision. For example, a company cannot make midyear adjustments to respond to market fluctuations, and the programs cannot be used to bridge temporary gaps in coverage or serve as quick promotions to capture revenue.

By requiring a full year, OIG is effectively forcing manufacturers to subsidize the patient's care long enough to ensure the program isn't just a loss leader to get a patient onto a drug before switching them to federal healthcare program billing.

This might not come as any surprise to those who spend great deals of time analyzing OIG advisory opinions, but the companies who ultimately are caught by the DOJ will end up committing these sorts of seeding errors.

Another restrictive element is the clear prohibition on using a DTC program to market other federally reimbursable products or services.

This might not seem controversial, but the government is making very clear that leveraging the sale of one product through a DTC channel may not serve as a way to promote the purchase of additional items — such as other prescription drugs or medical services — that are eligible for reimbursement by federal healthcare programs. The OIG's emphasis on this point should be construed broadly, or else the special advisory bulletin would not have included it.

The special advisory bulletin also highlights the need to protect patient safety, encouraging manufacturers to establish communication channels with the patient's federal healthcare program plan to minimize duplicative or contraindicated prescriptions. In the OIG's eyes, this factor allows for appropriate drug utilization review and medication therapy management, but the SAB is otherwise scant on details here.

The three-sided system — manufacturers, prescribers and pharmacies — underlying the market shifted fundamentally when telehealth prescribing and access loosened and the American consumer chose metabolic therapeutics en masse.

Historically, drug access was not always straightforward — a convoluted mess in part because a patient had to see their prescriber and ask for a product by name, then suffer the whims of insurer coverage criteria and other roadblocks to product access.

As these hurdles have changed over the years, the government has joined in — officially

and strategically — to advance this bold new clearinghouse for patient access to the medicines they want and deserve.

Compliance Tips

There is no turning back, so what should companies do — at a minimum — from a legal, compliance and regulatory perspective when preparing to join the party?

Analyze and Audit Telehealth Partnerships

Assess whether clinical protocols support true independence and scrutinize prescription patterns.

If a telehealth partner issues an unusually high rate of prescriptions for your products, or if the connections between the providers, practices and service organizations are confusing, review is warranted. High prescription rates or lack of genuine physician involvement increase risk and can undermine the independent, third-party prescriber requirement.

Evaluate Platform Compliance, Program Terms and Impact on Adjacent Business

If participating in TrumpRx, ensure platform characteristics mirror the special advisory bulletin perfectly, as any deviation opens the organization up to DOJ scrutiny.

Additionally, ensure that all DTC program terms and conditions guarantee price availability for the entire plan year and assess whether these programs could affect adjacent, federally reimbursed business lines.

Pay special attention to titration products — if the DTC price only covers a starter dose, this may fall outside low-risk protections and could be deemed as market seeding.

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should not be taken as legal advice.

[1] https://www.fiercepharma.com/pharma/pfizer-plans-direct-to-consumer-lipitor-sales.

[2] See Telehealth Company Cerebral Agrees to Pay Over $3.6 Million in Connection With Business Practices That Encouraged the Unauthorized Distribution of Controlled Substances, U.S. Dep't of Justice, U.S. Attorney's Office, E.D.N.Y. (Nov. 4, 2024).

[3] https://www.whitehouse.gov/fact-sheets/2026/02/fact-sheet-president-donald-j-trump-launches-trumprx-gov-to-bring-lower-drug-prices-to-american-patients/.

[4] https://oig.hhs.gov/compliance/alerts/#special-advisory-bulletins.

[5] https://www.hhs.gov/press-room/oig-clears-path-for-lower-cost-prescription-drugs.html.

[6] https://www.durbin.senate.gov/imo/media/doc/durbin_hhs_oig_letter_on_trumprx.pdf.

[7] See Durbin Leads Senators in Demanding Answers From Pfizer, Eli Lilly on New Telehealth Platforms Amid Concerns of Inappropriate Prescribing, U.S. Senator Dick Durbin (Oct. 22, 2024); Durbin, Warren, Welch, Sanders Demand Answers From Telehealth Companies Regarding Their Financial Relationship With Pfizer, Eli Lilly Amid Concerns Of Inappropriate Prescribing, U.S. Senator Dick Durbin (Mar. 11, 2025).

[8] See Durbin, Sanders, Warren, Welch Release Investigative Report On Pharma's New Direct-to-Consumer Telehealth Platforms, U.S. Senator Dick Durbin (July 17, 2025).