United States Senate

WASHINGTON, DC 20510

January 29, 2026

T. March Bell
Inspector General
U.S. Department of Health and Human Services
Office of Inspector General
330 Indepenence Ave, SW
Washington, DC 20201:

Dear Inspector General Bell:

We write to express concern with how the Department of Health and Human Services (HHS) Office of Inspector General (OIG) intends to conduct oversight of and apply the federal Anti-Kickback Statute to direct-to-consumer (DTC) prescription drug sales by manufacturers. On January 27, 2026, HHS OIG published a guidance document just days before the White House plans to launch the "TrumpRx" website, which will incorporate drug manufacturers' DTC platforms. While HHS stated that the January 27 guidance document "clears [the] path" for the TrumpRx website, we do not believe HHS OIG has adequately addressed whether TrumpRx and affiliated DTC platforms will be compliant with federal law, including the Anti-Kickback Statute. We believe the characteristics of the TrumpRx website require further HHS OIG review prior to launch of this government program.

The January 27 guidance document stipulates that certain characteristics of a DTC platform could "minimize the risk of fraud and abuse under the Federal anti-kickback statute" that is presented by a manufacturer participating in TrumpRx. This includes that: (1) a patient has a valid prescription from an independent, third-party prescriber; (2) no claims are submitted to Medicare (or any other federal health care program) for purchases through the DTC platform; (3) the manufacturer does not use the DTC platform as a vehicle to market other federally reimbursable products; (4) the manufacturer does not condition the DTC platform price on any future purchases; and (5) the manufacturer makes the prescription drug available to enrollees in its DTC program for at least one full plan year. We do not believe that all existing DTC platforms meet these criteria.

Considering the White House press conferences with drug manufacturers to tout participation in a website bearing the President's name, the Trump Administration clearly wants to give the appearance of lowering prices for patients. But there appear to be possible conflicts of interest involved in the potential relationship between TrumpRx and an online dispensing company, BlinkRx, on whose Board the President's son, Donald Trump, Jr., has sat since February 2025. Moreover, legitimate concerns about inappropriate prescribing, conflicts of interest, and inadequate care have been raised about the exact types of DTC platforms to which TrumpRx would route patients.

Last year, we released a report on an investigation of Eli Lilly's and Pfizer's DTC platforms, and their use of hand-picked telehealth companies to steer patients toward their own specific, high-cost medications. We found that Eli Lilly and Pfizer spent up to $3 million combined for partnerships with telehealth companies, who funneled patients to the

manufacturers' products. Under these arrangements, virtual visits resulted in a high rate of prescriptions issued—as the telehealth appointments often were cursory and with limited to not physician involvement. In one instance, 100 percent of the patients routed to a virtual visit with one of Eli Lilly's chosen telehealth companies received a prescription. If manufacturers continue to use affiliated telehealth companies for their DTC platforms under TrumpRx, it is not clear whether these prescriptions could be considered, "from an independent, third-party prescriber."

In addition, the pharmaceutical manufacturers who will reportedly be participating in TrumpRx have spent billions of dollars in combined advertising expenses for drugs sold on existing DTC platforms. As President Trump and HHS Secretary Kennedy have acknowledged, the pharmaceutical industry's outrageous DTC advertisements fuel demand for specific medications, which balloon health care expenses. We are concerned that DTC advertising, including in relation to TrumpRx, will steer customers to prescriptions that may be reimbursed by federal health programs, creating the potential for unnecessary or wasteful spending.

Given that oversight requests from Congress for information about the scope, structure, and legal authority underpinning the TrumpRx website have gone unanswered by HHS, and due to the lack of clarity with how HHS OIG will conduct oversight of a manufacturer's DTC platform that is embedded in the TrumpRx website, we cannot be sure that TrumpRx will comply with existing federal laws. Because of the practices that some pharmaceutical manufacturers have used to advertise and steer patients, we believe additional safeguards and transparency are required for any ".gov" website that will be promoted extensively by the White House and pharmaceutical manufacturers. We request responses to the following questions by February 15, 2026, or prior to the launch of the TrumpRx.gov website, whichever is earlier.

1. Will advertisements or promotions by pharmaceutical manufacturers touting their participation in or offerings on the TrumpRx website require adherence to the principles included in the guidance document?
    a. Will manufacturers be required to make statements regarding insurance coverage, pricing, or the requirement to first obtain a valid prescription from an independent, third-party prescriber in their advertising regarding TrumpRx?

2. In 2022, the HHS OIG issued a Special Fraud Alert to notify health care practitioners of the specific risks of schemes involving telehealth platforms that "intentionally paid physicians … kickbacks to generate … prescriptions for medically unnecessary … medications, resulting in submission of fraudulent claims to Medicare." HHS OIG noted that fraudulent aspects of these arrangements for prescribers may include: limited interaction with the purported patient, limited opportunity to review the patient's medical records, and/or a directive to prescribe a preselected item, regardless of clinical appropriateness. Manufacturer DTC platforms that may be linked to via TrumpRx appear to reflect many aspects of this 2022 warning for potential fraud.
    a. Will the TrumpRx website vet manufacturers' DTC arrangements with telehealth companies to ensure consistency with the 2022 Special Fraud Alert?
    b. How will the HHS OIG evaluate and ensure compliance with the provision in the January 27 guidance document—that an individual has a valid prescription from an independent, third-party prescriber—given the known risk of telehealth fraud?

3. Will the HHS OIG require that the TrumpRx website, as well as the participating pharmaceutical manufacturers, include notices to consumers regarding the January 27 guidance document's provision that no claims for drugs purchased via the DTC platform be submitted to any insurer, including Medicare?

4. Under their agreements with the White House, pharmaceutical manufacturers of certain GLP-1 medications appear to have agreed to sell "initial doses" of their medications for a discount on the TrumpRx website. However, patients typically initiate their regimens at lower doses prior to titrating up to higher maintenance doses.
    a. Would a situation in which a patient purchases a starting dose through a DTC platform linked via TrumpRx, then later seeks reimbursement for a higher dose through a federal health program, be in conflict with the January 27 guidance document?
    b. How will HHS OIG evaluate and ensure compliance with the provision in the January 27 guidance document that the manufacturer not use the DTC program for one product as a vehicle to market other federally reimbursable products?

5. TrumpRx could be used to steer patients to specific medications, potentially favoring one company's medications over another, depending on concessions companies have made to the White House as part of the deals, which still have not been made public. How has the HHS OIG advised the White House and HHS to depict different companies or their medications on the website to avoid steering patients to particular drugs?

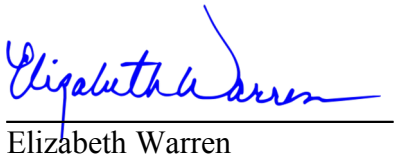
6. Which individuals did your office communicate with during preparation of the January 27 guidance document?
    a. Specifically, did your office communicate with any representative of BlinkRx, including with Donald Trump, Jr.?
    b. Did your office communicate with individuals from the White House? If so, please provide a list of all such individuals and the nature of the communication.
    c. What other outside entities did you consult with during the preparation of this guidance document? Please provide a complete list, including the nature of the communication.

Thank you for your attention to this matter. We look forward to your timely response.

Sincerely,

Richard J. Durbin
United States Senator

Peter Welch
United States Senator



Elizabeth Warren
United States Senator