

Direct-to-Patient Drug Sales Are Outpacing Telehealth Oversight

Where AI can help close the gap

By Natalia Vargas, MPH · October 2026

In brief. Drugmakers now sell directly to cash-paying patients, which can lower prices. Federal guidance covers the drug sales but not the telehealth arrangements around them. FDA and CMS already use AI to spot patterns, but not in this channel. Closing the gap takes agency action and new data-reporting authority.

What is changing

Platforms such as LillyDirect, NovoCare Pharmacy and PfizerForAll sell drugs directly to patients who pay cash. A direct sale skips the rebate arithmetic that a pharmacy benefit manager applies to a claim. Patients see a lower sticker price.

On January 27, 2026, the HHS Office of Inspector General issued a Special Advisory Bulletin on when these discounted cash sales pose low risk under the Anti-Kickback Statute. It does not address the telehealth arrangements connected to these programs, or the vendors that run them.

Why the gap matters

A 2025 Senate investigation reviewed Pfizer's and Eli Lilly's telehealth partnerships over nine months. Some visits took place without video. Clinicians often did not obtain the patient's medical record. At some partners, patients chose a medication before they spoke with a prescriber. Approval rates were 74 percent for LillyDirect and 85 percent for PfizerForAll. One smaller partner, Cove, approved all 15 of its virtual visits.

The exposure falls mostly on patients, independent prescribers and state medical boards. Manufacturers are several steps removed from the prescribing decision today. That could change if regulators act later.

Where AI can help

FDA has used an internal AI assistant, Elsa, since June 2025. It supports adverse event review, label comparison and inspection planning. CMS uses data analytics to flag unusual patterns in Medicare claims. A March 2026 GAO report says this work prevented about \$11.9 billion in potentially fraudulent payments between fiscal years 2022 and 2024.

Those systems work on claims, and a cash sale never generates one. To my knowledge, no federal AI tool looks at direct-to-patient sales data. An Elsa-style approach could take two new inputs: manufacturer reports of direct-to-patient transaction volumes, and basic telehealth metadata such as visit length and whether video was used.

Two more gaps

- **Corporate practice of medicine.** State laws limit non-physician control of prescribing. Eli Lilly has argued in court that telehealth companies selling compounded GLP-1 drugs violate California's version. A national platform must meet dozens of state standards.
- **Patient privacy.** HIPAA does not automatically cover a manufacturer's cash-pay web portal. The FTC fined GoodRx \$1.5 million in 2023 for sharing health data with advertisers. Washington State now applies a consent standard to any entity that collects health data.

What would close it

Agencies can start now. HHS and CMS could broaden the AI fraud-detection request for information they issued in February 2026 to name direct-to-patient and telehealth data. FDA could assess whether Elsa's inspection method extends to distribution.

Congress needs to act. No agency can currently compel manufacturers to report direct-to-patient transactions. A reporting requirement tied to OIG's low-risk conditions, with data use agreements, would give government the input its AI tools need without over-regulating the industry.

Direct-to-patient sales can lower what patients pay, and that goal is worth protecting. Clear policy built on shared public and private goals can keep patients at the center and bridge the gap between legislative intent and patient impact.

Working on an AI or health policy question at your organization? Themis Digital Health helps health organizations turn policy changes into practical plans. [Book a free 20-minute gap check](#) or email consulting@themisdigitalhealth.com.

Sources: [Ropes & Gray \(2026\) on the OIG Bulletin](#) · [Senate investigation \(Durbin, Sanders, Warren & Welch, 2025\)](#) · [Wouters, Fuse Brown & Mehrotra, NEJM \(2025\)](#) · [Definitive Healthcare on Elsa \(2025\)](#) · [GAO-26-107799 \(2026\)](#) · [HIPAA Journal on the RFI \(2026\)](#) · [Mintz on corporate practice of medicine \(2025\)](#) · [FTC on GoodRx \(2023\)](#) · [IAPP on Washington MHMDA](#). General information only; not legal advice.