Partnerships between Pharmaceutical and Telehealth Companies — Increasing Access or Driving Inappropriate Prescribing?

Erin C. Fuse Brown, J.D., M.P.H.,[1] Olivier J. Wouters, Ph.D.,[1] and Ateev Mehrotra, M.D., M.P.H.[1]

[1]Department of Health Services, Policy, and Practice, Brown University School of Public Health, Providence, RI

Americans have grown accustomed to direct-to-consumer pharmaceutical advertisements and the refrain, "If you think [this drug] is right for you, talk to your doctor." But some recent online ads feature a new twist — a direct link to a clinician offering telehealth services. Several pharmaceutical companies have also launched online platforms that direct users to websites run by telehealth companies, where clinicians are available to prescribe medications after a virtual consultation.

Pfizer's consumer-facing website, PfizerForAll, for example, prompts visitors to book same-day doctors' appointments offered by the telehealth company UpScript for $35. The website also offers copayment coupons to eligible patients to reduce out-of-pocket costs for Pfizer drugs. Eli Lilly's platform, LillyDirect, is focused on patients with diabetes, migraines, or obesity. The platform allows users to schedule a virtual appointment using the telehealth company Form Health and offers a home-delivery option for Eli Lilly medicines that are prescribed. Telehealth companies have also begun directly advertising pharmaceutical products on social media platforms, such as TikTok and Instagram. Form Health promoted an Eli Lilly drug on Instagram with a post reading: "When do you start losing weight on Zepbound?"

Debates about partnerships between pharmaceutical and telehealth firms have some parallels to long-standing arguments about direct-to-consumer drug advertising. Proponents highlight the potential for these partnerships between pharmaceutical and telehealth firms to facilitate access to prescriptions for some patients, such as those in rural areas who may struggle to get the care they need locally. Virtual consultations can be cheaper and less time-consuming for patients than in-person appointments. For stigmatized conditions such as obesity, patients may be more likely to seek care if they have access to a telehealth platform, which offers more privacy than a doctor's office.

But partnerships between drug and telehealth companies have prompted concerns as well. Several U.S. senators have written to pharmaceutical companies expressing alarm about the risks these arrangements pose in terms of inappropriate prescribing, inadequate follow-up care, and unnecessary spending on brand-name medications.[1] There is also concern that telehealth advertisements, including those on social media, may be misleading, since they sometimes lack disclosures of a product's risks and contraindications.

The key law governing these relationships in the United States is the federal Anti-Kickback Statute (AKS). The AKS is intended to prevent and penalize the use of financial incentives for patient referrals or other arrangements that encourage clinicians to provide inappropriate or unnecessary health care, thereby increasing government expenditures. It prohibits directly or indirectly offering or receiving remuneration to induce or in return for referrals for items or services that are reimbursable by Medicare, Medicaid, or other federal health care programs. The statute ascribes liability to both parties in such transactions and defines remuneration broadly as anything of value, including cash payments, discounts, copayment waivers, excess compensation, and in-kind goods and services. (Note: one of us has received consulting fees from a pharmaceutical company for consulting on telehealth partnerships.)

We suspect that many of these pharmaceutical–telehealth partnerships violate the AKS. Although regulators need more data on prescribing patterns to assess the potential for poor-quality care and patient harm associated with these arrangements, the Department of Health and Human Services Office of Inspector General (OIG) could influence industry behavior and support enforcement in this area by clarifying the types of financial arrangements that run afoul of the AKS.

Under the AKS, a pharmaceutical company cannot compensate a telehealth company or its affiliated clinicians on the basis of the number or monetary value of prescribed products. Nor may a telehealth company pay a pharmaceutical company for making patient referrals. In 2022, the OIG issued a special fraud alert about telehealth arrangements.[2] Although the alert focused on telehealth companies' arrangements with clinicians rather than partnerships with pharmaceutical companies, it cited concerns that financial incentives might prompt physicians offering telehealth services to prescribe medically unnecessary drugs, even when cheaper or safer options exist. The OIG also noted several characteristics of telehealth arrangements that heighten the risk of an AKS violation. These characteristics include patient recruitment using targeted advertising (including on social media), insufficient patient evaluation or follow-up, and steering of patients toward specific treatments without adequate consideration of clinical appropriateness or alternatives.

Some pharmaceutical–telehealth payment arrangements appear to skirt clear violations of the AKS's prohibition on payment for prescriptions or referrals. Pfizer reports that it pays a flat fee to its telehealth partner, UpScript, and Eli Lilly reports that it receives no compensation from its telehealth partners for referrals and doesn't offer incentives to third parties to prescribe its products.

A determination that flat-fee arrangements violate the AKS would require proof of intent to induce or reward referrals and would be supported by evidence in several areas related to the characteristics that the OIG flagged as potentially problematic. First, more information on prescribing patterns would help enforcers and regulators determine whether clinicians who work for telehealth companies are preferentially prescribing medications manufactured by partner pharmaceutical companies. A finding that the number of prescriptions written for a pharmaceutical partner's drugs is higher than would be expected in the absence of such an arrangement could suggest unlawful patient steering under the AKS. The senators' letter cited a statement by a leader of a telehealth company indicating that more than 90% of eligible patients received a prescription for the drug whose advertisement they clicked on, which drove up prescriptions for pharmaceutical companies.[1]

Second, evidence about the quality of care provided by telehealth companies under these arrangements is needed to determine whether patients are receiving adequate medical evaluation and follow-up. Systematic deviations from the standard of care might indicate that a telehealth company's prescriptions are financially motivated, rather than being based on clinical appropriateness, which would reflect an AKS violation. Although studies haven't evaluated the care provided under these partnerships, there is evidence that practitioners providing direct-to-consumer telehealth services prescribe antibiotics at higher rates than primary care clinicians at in-person visits.[3] One study, however, found that clinicians working for telehealth vendors effectively screened for contraindications to oral contraceptives.[4] In its special fraud alert, the OIG noted cases of clinicians who work for telehealth companies not conducting sufficient medical evaluation before prescribing medications or other items.[2]

Third, more information about the nature of financial arrangements between pharmaceutical and telehealth companies should be reported. Such reporting could be mandated as part of an expansion of the Physician Payments Sunshine Act. We believe that many of these arrangements could be unlawful under the AKS. Explicit guidance from the OIG — specifically addressing whether flat-fee arrangements constitute an unlawful exchange of value — could shape industry practice and enforcement. Other concerning arrangements may include those in which a pharmaceutical company refers patients to a telehealth partner in exchange for the partner engaging in advertising, patient recruitment, or inducements using copayment coupons; agreements whereby a pharmaceutical company provides speakers' fees or pays for educational programs for a telehealth company's prescribers; or partnerships in which a pharmaceutical company and the resulting stream of referrals enable a telehealth company to secure investor funding.

Beyond concerns about potential AKS violations, telehealth companies may be marketing their pharmaceutical partners' products to consumers without disclosing associated risks. The U.S. Food and Drug Administration regulates pharmaceutical companies' prescription-drug advertisements, requiring clear and conspicuous descriptions of side effects and contraindications.[5] But advertising by telehealth companies isn't subject the same regulations.

To address this gap, regulations could be expanded to cover telehealth companies that promote specific drugs using traditional or social media.

New partnerships between pharmaceutical and telehealth companies have raised alarm among researchers and legislators. Although these arrangements may improve access to care for some people, there are concerns that they may promote inappropriate care. Further evidence on care patterns and details about financial arrangements are needed. A successful policy response is likely to include stronger enforcement of the AKS and expanded rules for marketing pharmaceutical products on largely unregulated social media platforms.

Disclosure forms provided by the authors are available at NEJM.org.

References

1. Durbin leads senators in demanding answers from Pfizer, Eli Lilly on new telehealth platforms amid concerns of inappropriate prescribing. October 24, 2024 (https://www.durbin.senate.gov/newsroom/press-releases/durbin-leads-senators-in-demanding-answers-from-pfizer-eli-lilly-on-new-telehealth-platforms-amid-concerns-of-inappropriate-prescribing).

2. Office of Inspector General, U.S. Department of Health and Human Services. Special fraud alert: OIG alerts practitioners to exercise caution when entering into arrangements with purported telemedicine companies. July 20, 2022 (https://oig.hhs.gov/documents/root/1045/sfa-telefraud.pdf)

3. Ray KN, Shi Z, Gidengil CA, Poon SJ, Uscher-Pines L, Mehrotra A. Antibiotic prescribing during pediatric direct-to-consumer telemedicine visits. Pediatrics 2019;143:e20182491.

4. Jain T, Schwarz EB, Mehrotra A. A study of telecontraception. N Engl J Med 2019;381:1287-8.

5. Food and Drug Administration, U.S. Department of Health and Human Services. Direct-to-consumer prescription drug advertisements: Presentation of the major statement in a clear, conspicuous, and neutral manner in advertisements in television and radio format. November 21, 2023 (https://www.federalregister.gov/documents/2023/11/21/2023-25428/direct-to-consumer-prescription-drug-advertisements-presentation-of-the-major-statement-in-a-clear).