

Direct-to-Prescription Telehealth and the Corporatization of Medicine

Working Paper

February 2026

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ABSTRACT

Direct-to-Prescription (DTP) models exploit the convergence of three long-standing trends: decades of direct-to-consumer drug advertising, the rapid normalization of telehealth, and the growth of affiliated mail-order pharmacies. Together, these developments enable prescription-on-demand systems in which patients are steered—often by manufacturer-linked advertising—toward platforms designed to convert consumer demand into recurring pharmaceutical utilization. In these settings, physicians function less as independent fiduciaries and more as transactional intermediaries within vertically integrated commercial pipelines. The resulting conflicts of interest threaten patient safety, fragment care, and drive unsustainable spending, while eroding the relational foundations of the physician-patient relationship.

The Article demonstrates that existing legal tools are poorly calibrated to address these structural risks. Fraud-and-abuse statutes such as the Anti-Kickback Statute require fact-dependent proof of unlawful intent and payment by federal health care programs, leaving the deeper relational and professional harms largely untouched. Meanwhile, state licensing and corporate practice of medicine doctrines have been weakened by under-

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enforcement and contractual evasion. Refocusing regulation on the physician-patient relationship as a protected professional institution, the Article proposes a hybrid response: clear state medical board prohibitions on physicians' financial entanglement with entities that profit from prescribing decisions, coupled with a targeted federal statute that would prohibit conflicted prescription-writing and support enforcement through the False Claims Act. Absent such intervention, the commercialization of prescribing threatens not only patient safety and public spending, but the integrity of medical judgment itself.

INTRODUCTION

In August 2022, Luke Tyler, a nineteen-year old freshman at Washington State University, clicked on an ad on Instagram for Hims & Hers (Hims), an online telehealth company.¹ Within twelve minutes, Luke had created a profile, filled out an online questionnaire, and messaged a Hims provider that he was seeking medication for “undiagnosed depression with bad self-harm habits.”² Thirty-six minutes later and without any virtual, live evaluation, Luke received a ninety-day prescription for 150mg per day of bupropion from Hims that would automatically renew every three months, shipped directly to him from the Hims's mail-order pharmacy. Bupropion is the generic name for Wellbutrin, an FDA-approved drug used to treat major depressive disorder that carries a black box warning for an increased risk of suicidal ideation and behavior in children, adolescents, and young adults up to age twenty-four.³

Hims never contacted Luke or followed up with him, but Luke messaged Hims a month later, on September 27, 2022, noting that his symptoms were not improving and that he had been feeling more irritable.⁴

¹ Mitchell Roland, *Family Files Lawsuit Against Telehealth Company They Say Contributed to WSU Student's Suicide*, SPOKESMAN-REV. (Nov. 13, 2025, at 17:53 ET), <https://www.spokesman.com/stories/2025/nov/13/family-files-lawsuit-against-telehealth-company-th/>.

² Complaint at 3, Tyler v. Hims & Hers Health, Inc., No. 25-2-33855-0 KNT (Wash. Super. Ct. Nov. 12, 2025), <https://bloximages.newyork1.vip.townnews.com/kxly.com/content/tncms/assets/v3/editorial/1/9/1491420d26-018b-48cb-89d8-aea887e895f3/691632e31fcf4.pdf.pdf>.

³ FDA, PRESCRIBING INFORMATION: WELLBUTRIN XL 4 (2009), https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021515s023s024lbl.pdf.

⁴ Complaint, *supra* note 2, at 3 para. 1.7.

Without any further evaluation or live interaction with a provider, Hims doubled his dosage to 300mg per day of bupropion, again automatically shipping and refilling every three months, despite Luke still possessing most of his original medication. On November 15, 2022, Luke again messaged Hims, complaining that the “meds seemed to make [his] condition worse” and asked to cancel his subscription.⁵ Again, without any real-time medical consultation with Luke, the providers on the Hims platform assured him that he would not need to taper his dosage to avoid side effects since he had already stopped taking the medication.

Luke’s mental state continued to deteriorate, perhaps exacerbated by the stress of undergoing hazing from pledging a fraternity at school. On January 22, 2023, Luke took large number of his remaining bupropion pills and died by suicide in his dorm room. Luke’s family filed a wrongful death lawsuit against Hims & Hers and its affiliated medical groups.⁶ Among the allegations was that the Hims prescriber was incentivized to fill as many prescriptions as possible, and thus negligently increased Luke’s prescription without appropriate evaluation or monitoring and failed to disclose the risks of suicide.⁷

A new model of health care has emerged, offering the opportunity to quickly and easily satisfy patient desire for prescriptions while upending the doctor-patient relationship. While acquiring a prescription historically required a visit to and a conversation with a physician, drugs are now advertised in conjunction with websites enabling the patient to obtain the advertised prescription in minutes. Now, partnerships between pharmaceutical and telehealth companies are taking these prescription-on-demand arrangements—which we refer to as the Direct-to-Prescription (DTP) Model—a dangerous step further, driving increased use for expensive, high-demand prescriptions, such as GLP-1s. While these partnerships may improve access and convenience, they also raise questions about inappropriate prescribing, patient-steering, spending increases, and erosion of the physician-patient relationship. Policymakers and scholars have increasingly expressed concern and called for safeguards against the influence of these arrangements, yet none have been forthcoming.

Through direct-to-consumer advertising over nearly three decades,

⁵ Complaint, *supra* note 2, at 31 para. 3.66.

⁶ Complaint, *supra* note 2, at 31 para. 3.61.

⁷ Complaint, *supra* note 2, at 31 para. 3.61.

pharmaceutical manufacturers have successfully changed the role of health care consumers. Whether spurred by advertising or by their own internet-powered research, consumers are increasingly empowered to take an active role in their own care. But with that empowerment, as changes in the health care system have led fewer patients to have meaningful, long-term relationships with their physicians, patients' have decreased their perceived value of physician judgment and advice. At the same time, advances in technology have helped spur a rapid increase in telehealth, and there has been substantial growth in internet-based pharmacies offering to fulfill and deliver prescribed medication.

Because of these developments, DTP arrangements have risen rapidly in recent years. These models typically involve companies advertising specific drugs and steering patients to online platforms for brief clinical consultations, after which prescriptions are dispensed, often with the drugs delivered to the patient via affiliated mail-order pharmacies. A Super Bowl television commercial described one such platform as “the future of healthcare” in a “broken” health care system.⁸ No longer tied to their own doctor or needing an office visit, patients are instead directed to websites promising quick, easy, “personalized treatment” focused on “free consultations” with “licensed providers.”⁹ It is understood the “licensed providers” are eager to write the prescription the consumer has come to the website to receive—the consultations are free but the drugs are not, and the provider's employer makes money not based on charging for the patient visit and consultation (the way a typical physician practice makes money), but based on charging for drugs through the vertically integrated pharmacy.

Not surprisingly, pharmaceutical manufacturers have combined the two—not only advertising products directly to consumers, but also providing a quick and easy pathway for consumers to obtain those products through online platforms connected to the manufacturer. The relationship is a revenue-generating dream for pharmaceutical manufacturers. While in some DTP arrangements the prescriptions are delivered to the patient via an affiliated mail-order pharmacy and the DTP entity draws its revenue from the filling of the prescription, a pharmaceutical manufacturer need not affiliate with a pharmacy to make money from the model—they are encouraging and facilitating the obtaining of prescriptions for *their* drug and will make money wherever the prescription is filled.

⁸ HERS, *Hims & Hers Big Game Commercial: “Sick of the System,”* (YouTube, Jan. 28, 2025), <https://www.youtube.com/watch?v=15l6QMnqoc>.

⁹ E.g., HIMS, <https://www.hims.com> (last visited Dec. 17, 2025).

Unlike a physician working in a traditional practice—who decides whether to prescribe a drug from a place of financial detachment (they are paid for the office visit, regardless)—the DTP tele-prescribing doctor is employed by an entity that only makes money when a prescription is written. The doctor can be told to exercise appropriate medical judgment and only prescribe when necessary, but they cannot help but know where their bread is buttered. What’s more, the doctor is only presented with the patient after the doctor’s employer has concluded, through a web questionnaire, that the patient *should* receive the requested drug. In some cases, the doctor or nurse practitioner do not even evaluate the patient in real-time but simply sign off on the prescription based on the questionnaire.

The result is a model that distorts the physician-patient relationship, with patients expecting prescriptions on demand—often prescriptions they are seeking based on manufacturer advertising—and prescribers with only minimal connection to the prescription-seeking patient. The evolving relationship between doctor and patient extends beyond the bounds of the model itself, potentially shifting patient expectations about care in traditional settings. The transactional nature of the DTP relationship further fragments patient care, with patients presenting to their usual clinicians with side effects or drug interactions from drugs undisclosed to and unsupervised by their regular doctors.

This Article reveals that no existing law adequately addresses the range of concerns posed by these arrangements. While increasingly expressing alarm and criticism of the partnerships, policymakers are seemingly at a loss as to how to address the problem.¹⁰ The most obvious legal tool, the Anti-Kickback Statute, can be easily circumvented by sophisticated contracting arrangements and only applies when federal health program payments are involved, and thus may be poorly calibrated to address the care quality and relational concerns of these partnerships. This Article argues that state medical boards’ disciplinary and licensing authority may be used to address potential inappropriate and substandard care provided by telehealth providers under these arrangements. Yet, the state professional licensing standards and corporate practice of medicine prohibitions are likely under-resourced to address a national issue and may not reach the critical actors behind these arrangements—the pharmaceutical companies. This

¹⁰ See generally RICHARD J. DURBIN, BERNARD SANDERS, ELIZABETH WARREN & PETER WELCH, BIG PHARMA’S NEW SALES SCHEME: EXPANDING PATIENT ACCESS OR A VIRTUAL PILL MILL? (2025), <https://www.durbin.senate.gov/imo/media/doc/DTC%20Investigation%202025.pdf>.

Article proposes a new federal statute and explores ways to link existing state law standards, including medical standards of care and the prohibitions on the corporate practice of medicine, to federal False Claims Act liability to create a hybrid enforcement pathway to address abuses of these lucrative arrangements.

This Article describes the risks posed by the growth of the DTP Model and analyzes potential legal solutions to address the range of concerns posed by these arrangements. Part I details the evolution from the growth of direct-to-consumer advertising through to the DTP Model seen today, aided by advancements in telehealth and changes in the health care system. Part II examines the existing legal tools proposed to address the negative impact of the DTP Model, including the Anti-Kickback Statute, finding all of them insufficient. Part III offers policy proposals aimed at controlling the risks associated with the DTP Model, while maintaining the substantial benefits which grow out of telemedicine and the empowerment of patients. The conclusion puts the model's growth in the context of broader issues of the corporatization of medicine.

I. THE DIRECT-TO-PRESCRIPTION MODEL

Direct-to-Prescription (DTP) models are arrangements in which advertisements not only encourage prospective patients to desire a particular drug, but also to obtain that drug through online telehealth platforms where clinicians are available to prescribe medications following a brief virtual consultation. Often, prescriptions are delivered to the patient via an affiliated mail-order pharmacy. Increasingly, these arrangements are driven by pharmaceutical companies using the DTP Model to bypass patients' primary care doctors. These arrangements, which have emerged in recent years, reflect three distinct trends: (1) the growth of direct-to-consumer (DTC) advertising by pharmaceutical drug manufacturers; (2) increased use of telehealth by patients to receive health care services and prescriptions; and (3) use of vertically integrated pharmacies to fulfill and deliver the prescribed medication. This Part traces these trends, provides illustrative examples of DTP arrangements, and assesses both the potential benefits and concerns they raise.

A. The Emergence of the DTP Tele-Prescribing Model

At its increasingly present extreme, DTP tele-prescribing vertically integrates the entire prescription drug delivery chain from manufacturer to the patient. These arrangements combine DTC marketing,

telehealth, and affiliated mail-order pharmacies to provide a single end-to-end process for consumers to access sought-after prescription drugs. A television or internet advertisement can convince a patient to desire a drug, anytime day or night, and minutes later a prescription is written and the drug is on its way to the patient's mailbox. The DTP Model emerged from the intersection of three forces: the long-standing expansion of pharmaceutical DTC advertising, the rapid normalization of telehealth, and the integration of affiliated mail-order pharmacies.

For nearly three decades, pharmaceutical manufacturers have used DTC advertising to increase their sales and revenues. Since the loosening of the FDA regulations in 1997 that permitted drug makers to market to consumers directly, pharmaceutical advertising expenses have increased steadily every year, totaling \$729.4 million on TV commercials for the ten top-performing branded drugs in the first quarter of 2025.¹¹ The amount pharmaceutical companies spend on advertising is positively correlated with the number of prescriptions they expect to sell, and in turn, their anticipated profits. The Congressional Budget Office estimates that a 10% increase in DTC marketing leads to a 1 to 2.3% increase in overall drug spending,¹² while separate research found that the same ad spending increased sales of the advertised medications by 5.4%.¹³

Proponents of DTC pharmaceutical marketing emphasize that it educates consumers and allows individuals to take greater ownership over their health. Advertisements use phrases such as “Talk to a doctor now” and “You deserve to feel better” to encourage and empower patients to actively seek out medications to manage their symptoms or known illnesses.¹⁴

¹¹ Robert H. Shmerling, *Harvard Health Ad Watch: How Direct-to-Consumer Ads Hook Us*, HARV. HEALTH PUBL'G (Apr. 3, 2025), <https://www.health.harvard.edu/blog/harvard-health-ad-watch-how-direct-to-consumer-ads-hook-us-201909201968>; Andrea Park, *TV Drug Ad Spending Continues Upward Climb, Logging Nearly 30% Growth in Q1*, FIERCE PHARMA (Apr. 17, 2025, at 11:43 ET), <https://www.fiercepharma.com/marketing/fda-untitled-letter-skewers-esperions-claims-about-cholesterol-med-nexlizet-tv-ad>.

¹² CONG. BUDGET OFF., ALTERNATIVE APPROACHES TO REDUCING PRESCRIPTION DRUG PRICES 28–29 (Oct. 2024), <https://www.cbo.gov/system/files/2024-10/58793-rx-drug-prices.pdf>.

¹³ Abby Alpert, Darius Lakdawalla & Neeraj Sood, *Prescription Drug Advertising and Drug Utilization: The Role of Medicare Part D*, 221 J. PUB. ECON. 104860, at 2 (2023), [<https://doi.org/10.1016/j.jpubeco.2023.104860>].

¹⁴ Katie Palmer, *This Is Pharma's Dream': How Drugmakers Are Turning Telehealth into a Marketing Gold Mine*, STAT (Sep. 14, 2022),

However, critics have warned that many of the most heavily advertised drugs fail to offer even modest advantages over their alternatives but may increase health care costs and spending from greater utilization of more expensive drugs.¹⁵

The second trend that gave rise to the DTP Model is the normalization of telehealth. Telehealth refers to the delivery of health information and services through electronic and telecommunication technologies—such as computers, smartphones, and tablets—that allow individuals to consult providers remotely.¹⁶ The Covid-19 pandemic spurred dramatic growth in the availability and usage of telehealth services—primarily via legislative changes that temporarily expanded Medicare coverage of telehealth visits.¹⁷ Beyond Medicare, the pandemic also spurred many states to loosen state licensing requirements for telehealth, including through broader adoption of interstate licensing compacts and other forms of certification.¹⁸ Telehealth, once a niche modality, became a mainstream vehicle for medical consultation as emergency waivers expanded reimbursement and state licensure flexibility.¹⁹

Even as pandemic restrictions waned, telemedicine remained embedded in health-care financing and practice,²⁰ attracting substantial

<https://www.statnews.com/2022/09/14/pharma-marketing-prescriptions-telehealth-virtual/>.

¹⁵ Robert H. Shmerling, *Rating the Drugs in Drug Ads*, HARV. HEALTH PUBL'G (Jan. 31, 2023), <https://www.health.harvard.edu/blog/rating-the-drugs-in-drug-ads-202301312883>.

¹⁶ *Why Use Telehealth?*, TELEHEALTH.HHS.GOV (July 29, 2025), <https://telehealth.hhs.gov/patients/why-use-telehealth>.

¹⁷ Zachary J. Peters et al., *Telemedicine Use During the COVID-19 Pandemic by Office-Based Physicians and Long-Term Care Providers*, NAT'L HEALTH STAT. REPS. NO. 210, at 1 (2024), [<https://doi.org/10.15620/cdc/159282>]. The Medicare waivers expire on January 30, 2026, so starting January 31, 2026, patients must be located in an office or medical facility in a rural area to be reimbursed for most telehealth services. *Telehealth*, MEDICARE.GOV, <https://www.medicare.gov/coverage/telehealth> (last visited Jan. 10, 2026).

¹⁸ Tara Sklar, *Pursuing an Interstate Medical Telemedicine Registration Compact*, Bill of Health, Petrie Flom Center at Harvard Law, Sept. 6, 2024, <https://petrieflom.law.harvard.edu/2024/09/06/pursuing-an-interstate-medical-telemedicine-registration-compact/>.

¹⁹ *Telehealth Private Insurance Laws*, NAT'L CONF. OF STATE LEGISLATURES (Oct. 24, 2024), <https://www.ncsl.org/health/the-telehealth-explainer-series/telehealth-private-insurance-laws>.

²⁰ Grace Halsey, *Telehealth May Represent Up to 30% of US Medical Visits by*

venture capital and private-equity investment.²¹ Traditional “brick and mortar” health care entities, such as insurers and providers, expanded their telehealth infrastructure.²² Often these ventures involve partnerships with established telehealth companies such as Teladoc, Amwell, or and Talkiatry, which offer virtual health care provider visits.

Telehealth companies such as Hims & Hers, Ro, and 9amHealth leveraged this growing telehealth infrastructure to build vertically integrated businesses that added integrated pharmacy fulfilment.²³ Thus emerged the DTP telehealth platform, which combines online advertising, telehealth encounters, and often in-house or contracted pharmacy dispensing. Often these platforms would target certain conditions, such as drugs for erectile

2026, PATIENT CARE (May 27, 2025), <https://www.patientcareonline.com/view/telehealth-may-represent-up-to-30-of-us-medical-visits-by-2026>; 2024 National Telehealth Survey, PUB. OP. STRATEGIES (Mar. 4, 2024), <https://pos.org/2024-national-telehealth-survey/>; Alex Cottrill, Juliette Cubanski & Tricia Neuman, *What to Know About Medicare Coverage of Telehealth*, KFF (Oct. 2, 2024), <https://www.kff.org/medicare/issue-brief/what-to-know-about-medicare-coverage-of-telehealth/>.

²¹ 9amHealth, *9amHealth Raises \$9.5M Series A Extension Led by The Cigna Group Ventures to Expand to Employers Nationwide*, PR NEWswire (Feb. 20, 2024), <https://www.prnewswire.com/news-releases/9amhealth-raises-9-5m-series-a-extension-led-by-the-cigna-group-ventures-to-expand-to-employers-nationwide-302065577.html>.

²² Kaiser Permanente, a major American managed care organization based in California, recently developed its own Advanced Care at Home program to provide services such as telehealth visits with clinicians, 24/7 phone monitoring and prescription delivery. *Advanced Care at Home*, KAISER PERMANENTE, <https://healthy.kaiserpermanente.org/northern-california/learn/high-quality-care/advanced-care-at-home> (last visited Jan. 17, 2026). In November 2022, Optum Ventures, a venture capital firm owned by United Health Group, led a Series C funding round of \$259 million for DispatchHealth, which integrates telehealth to its on-demand hospital-at-home services. *DispatchHealth Raises More than \$330 Million to Expand Its Technology-Enabled Ecosystem of High Acuity Care in the Home*, DISPATCHHEALTH (Nov. 23, 2022), <https://www.dispatchhealth.com/press-room/dispatchhealth-raises-more-than-330-million-to-expand-its-technology-enabled-ecosystem-of-high-acuity-care-in-the-home/>. The same year, Aetna, owned by CVS Health, partnered with Teladoc’s Primary360 to begin offering virtual primary care services to its clients. *Teladoc Health Reimagines Primary Care with Primary360*, TELADOC HEALTH (Oct. 6, 2021), <https://www.teladochealth.com/newsroom/press/teladoc-health-reimagines-primary-care-with-primary360>.

²³ Katie Palmer, *From Erectile Dysfunction to Weight Loss, How Telehealth Got Hooked on Drug-First Thinking*, STAT (Oct. 6, 2025), <https://www.statnews.com/2025/10/06/telehealth-companies-shift-from-providing-patient-access-to-selling-drugs/>.

dysfunction, hair loss, sexual health, or weight loss, for which there is a ready cash-pay market because the conditions are stigmatized, not covered by insurance, or both. Investors and pharmaceutical manufacturers alike recognized the model's revenue prospects: it converts advertising exposure directly into prescription and dispensing revenue within a single digital ecosystem.²⁴ Because of state prohibitions on the corporate practice of medicine, DTP telehealth platforms do not employ physicians to furnish the clinical evaluation and prescription.²⁵ Rather, telehealth platforms function as management services organizations that contract with affiliated professional corporations, often on an exclusive basis, to provide clinicians licensed in all 50 states to perform the virtual clinical evaluations.²⁶ A Hims & Hers's 2025 annual investor report filed with the Securities and Exchange Commission is illustrative, describing their business strategy as follows:

We offer access to a range of health and wellness products and services available for customers to purchase through our websites and mobile applications. The offerings generally focus on conditions where treatment typically involves use of prescription medication on a recurring basis and ongoing care from healthcare providers. *We offer access to certain prescription generic, brand-name and compounded medications, including certain sterile compounded medications. The majority of prescriptions for these medications are fulfilled through our affiliated pharmacies. . .*

Due to the prohibition on the corporate practice of medicine adopted by a majority of states in the U.S., we have contractual arrangements with Affiliated Medical Groups to enable their provision of clinical services to our customers. . .

²⁴ See *Hims & Hers and Novo Nordisk Team Up to Expand Affordable Access to Care*, HIMS & HERS NEWSROOM (Apr. 29, 2025), <https://news.hims.com/newsroom/hims-hers-and-novo-nordisk-team-up-to-expand-affordable-access-to-care>; Heather Landi, *Ro Teams Up with Eli Lilly to Offer Single-Dose Vials of Weight Loss Drug Zepbound*, FIERCE HEALTHCARE (Dec. 12, 2024, at 8:00 ET), <https://www.fiercehealthcare.com/providers/ro-teams-eli-lilly-offer-single-dose-vials-weight-loss-drug-zepbound>.

²⁵ Hims & Hers Health, Inc., Annual Report (Form 10-K) 2, 4–5 (Feb. 24, 2025).

²⁶ U.S. Dep't of Health & Hum. Servs., Off. of Inspector Gen., *OIG Advisory Op. No. 25-03* (June 11, 2025) (describing a proposed arrangement where platform functions as an MSO to contract with certain professional corporations (PCs) to provide clinical telehealth services to the platform's patients).

While we are prohibited from owning a professional entity such as any of the Affiliated Medical Groups, the *Affiliated Medical Groups were incorporated and established with our assistance for the specific purpose of providing clinical services to patients through the Hims & Hers platform and have no other operations or activities outside of the provision of services through the Hims & Hers platform.*

The Affiliated Medical Groups contract with or employ physicians, nurse practitioners, physician assistants, and behavioral health providers (each, a “Provider”) to provide telehealth consultations and related services on the Hims & Hers platform. . . . *We are the exclusive administrative services provider for the Affiliated Medical Groups, and the Affiliated Medical Groups provide services to patients exclusively through the Hims & Hers platform.*²⁷

The market evolution did not end there. Pharmaceutical manufacturers began partnering with DTP telehealth companies to align the entire pharmaceutical delivery chain—from marketing and diagnosis to prescribing and distribution. The DTP tele-prescribing model is leading to an important shift in the way pharmaceutical manufacturers identify, attract, and sell their products to patients. These marketing campaigns often take the form of manufacturer websites or other online platforms that advertise specific medications, prompting users to click the link to a partnering telehealth company’s website where patients complete a screening questionnaire and clinicians can easily write prescriptions via quick, virtual appointments.²⁸ Often, these visits may last a few minutes, and in some cases may occur asynchronously. Patients may pay for prescriptions obtained through the DTP telehealth encounter via cash or submit claims for insurance reimbursement—often aided by manufacturer coupons.

Two prominent examples of such arrangements include Eli Lilly’s *LillyDirect* and Pfizer’s *PfizerForAll*. Launched in January 2024, the *LillyDirect* platform links patients to selected telehealth partners focusing on specific Lilly products—offering diabetes care (Humalog) through 9amHealth, migraine treatment (Emgality) through Cove, and obesity

²⁷ Hims & Hers Health Inc., *supra* note 25, at 2–5 (emphasis added).

²⁸ Michelle Onder & Michael S. Sinha, *Pharmaceutical-Telehealth Confederacies*, 12 EMORY CORP. GOVERNANCE & ACCOUNTABILITY REV. (forthcoming), [https://dx.doi.org/10.2139/ssrn.5202666].

management (Zepbound) through Form Health and 9amHealth.²⁹ PfizerForAll was launched in partnership with telehealth company UpScriptHealth in August 2024 with the publicized objective to make health care more accessible and affordable for individuals experiencing common conditions such as migraines or menopause.³⁰ Pfizer contracts with Alto Pharmacy and Instacart to allow consumers to access drugs and over-the-counter diagnostic tests through pick up or same-day delivery.³¹

These relationships may cause physicians to prescribe more drugs, and more of their partner company's branded drugs, than they might otherwise. A 2025 Senate investigative report published by Senators Durbin, Sanders, Warren, and Welch found that 85% of patients who interacted with a provider via UpScriptHealth received prescriptions, as did 100% of those that used Cove—one of Lilly's telehealth partners alongside 9amHealth, Form Health and Nourish.³² The Senate report stated that providers on 9amHealth were six times more likely to prescribe Eli Lilly drugs than other similar branded drugs, and around one-third of all patients using Form Health were given Eli Lilly medications.³³

The same report also revealed that pharmaceutical companies invest heavily in these arrangements. Pfizer, along with others, is paying between \$510,000 and \$2.45 million to one of its telehealth providers over the three-year contract period, while three of Eli Lilly's telehealth partners combined charge the manufacturer \$942,500.³⁴ These findings highlight the mutually

²⁹ DURBIN ET AL., *supra* note 10, at 3; Richard Payerchin, *Lilly Launches Direct-to-Patient Telehealth Service*, MED. ECON. (Jan. 5, 2024), <https://www.medicaleconomics.com/view/lilly-launches-direct-to-patient-telehealth-service>.

³⁰ *Pfizer Launches PfizerForAll™, a Digital Platform that Helps Simplify Access to Healthcare*, PFIZER (Aug. 27, 2024), <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-launches-pfizerforalltm-digital-platform-helps>.

³¹ *Id.*

³² Press Release, Dick Durbin, Senator, Durbin, Sanders, Warren, Welch Release Investigative Report on Pharma's New Direct-to-Consumer Telehealth Platforms (July 17, 2025), <https://www.durbin.senate.gov/newsroom/press-releases/durbin-sanders-warren-welch-release-investigative-report-on-pharmas-new-direct-to-consumer-telehealth-platforms>.

³³ *Id.*

³⁴ Katie Palmer, *Senators Reveal How Much Lilly, Pfizer Paid Telehealth Companies*, STAT (July 17, 2025), <https://www.statnews.com/2025/07/17/senators-investigate-pharma-telehealth-payments-for-possible-kickbacks/>.

beneficial nature of pharma-telehealth partnerships and their tendency to induce potentially inappropriate and unnecessary prescribing, despite manufacturers' claims that physicians are fully empowered to exercise their own clinical judgement and make independent care decisions.³⁵

What distinguishes these new DTP arrangements from traditional telehealth services such as Teladoc or Amwell is their vertical integration of marketing, clinical evaluation, and often drug dispensing.³⁶ Traditional telehealth companies act as neutral intermediaries connecting patients and clinicians, with prescriptions typically routed to a pharmacy of the patient's choice.³⁷ Traditional telehealth providers primarily generate revenue through visit-based service fees.³⁸ By contrast, DTP tele-prescribing platforms generate revenue only when a prescription is written, often through automatic fulfillment through affiliated pharmacies³⁹—blurring the boundary between medical care and commercial promotion.⁴⁰ As discussed in Part II, this convergence introduces novel regulatory challenges under fraud and abuse laws, state medical practice and licensing requirements, and federal oversight of FDA-regulated promotional activity, all of which were designed for a far less integrated marketplace.

A recent lawsuit between Novo Nordisk and Hims & Hers highlights the financial incentives and potential conflicts of interest surrounding DTP

³⁵ Erin C. Fuse Brown, Olivier J. Wouters & Ateev Mehrotra, *Partnerships Between Pharmaceutical and Telehealth Companies — Increasing Access or Driving Inappropriate Prescribing?*, 392 NEJM 1148 (2025), [<https://doi.org/10.1056/NEJMp2500379>].

³⁶ Suzanne G. Bollmeier et al., *Direct to Consumer Telemedicine: Is Healthcare From Home Best?*, 117 MO MED 303 (2020), [https://doi.org/10.1007/978-3-030-53879-8_11].

³⁷ *How It Works*, AMWELL FOR PATIENTS, <https://patients.amwell.com/how-it-works> (last visited Jan. 17, 2026); *Teladoc Health Prescription Policy*, TELADOC HEALTH, <https://www.teladochealth.com/info/prescription-policy> (last visited Nov. 1, 2025).

³⁸ Bryan T. Arkwright, Monica Leslie & Morgan Light, *Telehealth Finance Variables and Successful Business Models*, 4 TELEHEALTH & MED. TODAY 1, 3 (2019), [<https://doi.org/10.30953/tmt.v4.140>].

³⁹ *How It Works*, RO, <https://ro.co/roman/how-it-works/> (last visited Nov. 1, 2025); Hims, *How a Telehealth Visit Actually Works*, MEDIUM: HIMES & HERS (Apr. 21, 2020), <https://medium.com/hims-hers/how-a-telehealth-visit-actually-works-f7ecc50d14e9>.

⁴⁰ Where a pharmaceutical manufacturer is involved in the arrangement, the model need not include fulfillment through an affiliated pharmacy in order to be financially lucrative—it is enough that it encourages prescriptions specifically for the manufacturer's drug.

pharma-telehealth platforms. In April 2025, Novo Nordisk began working with Hims to transition consumers from compounded versions of semaglutide—an anti-diabetic and obesity medication—to its branded and FDA-approved Wegovy.⁴¹ However, the collaboration ended at the end of June 2025 when Novo sued the telehealth provider, arguing that it continued to advertise cheaper knock-off alternatives while the drug was in short supply,⁴² to which Hims CEO responded by accusing Novo of making “anticompetitive demands.”⁴³ The conflict reveals the mutually beneficial financial exchange that underlie these partnerships (patient referrals in exchange for prescriptions), and belies the claim that these partnerships are designed not to interfere with clinicians’ prescription decisions. These developments have escalated concerns around the use of DTC marketing within pharma-telehealth partnerships and the health and safety risks associated with them.

In this manner, DTP telehealth companies represent an extreme version of a larger trend toward “corporatization” and investor-control of medical practices.⁴⁴ DTP telehealth companies are technology platforms that operate and control affiliated physicians to monetize virtual evaluations and prescriptions. This is perhaps different not in kind but in degree from other forms of corporatization of physician practices, such as a private equity - backed dermatology practice or an insurer-acquired primary care group.⁴⁵ In

⁴¹ *Hims & Hers and Novo Nordisk Team Up to Expand Affordable Access to Care*, *supra* note 24.

⁴² Novo Nordisk Inc., *Novo Nordisk Terminates Collaboration with Hims & Hers Health, Inc. Due to Concerns About Their Illegal Mass Compounding and Deceptive Marketing*, PR NEWswire (June 23, 2025), <https://www.prnewswire.com/news-releases/novo-nordisk-terminates-collaboration-with-hims--hers-health-inc-due-to-concerns-about-their-illegal-mass-compounding-and-deceptive-marketing-302488189.html>.

⁴³ Mike Scarcella, *Hims & Hers Hit with Investor Lawsuits After Novo Ends Wegovy Partnership*, REUTERS (July 15, 2025, at 18:21 EDT), <https://www.reuters.com/legal/government/hims-hers-hit-with-investor-lawsuits-after-novo-ends-wegovy-partnership-2025-07-15/>.

⁴⁴ Erin C. Fuse Brown, *Defining Health Care “Corporatization,”* 393 N ENGL J MED 1 (2025), <http://www.nejm.org/doi/10.1056/NEJMp2415485>

⁴⁵ See e.g., Erin C. Fuse Brown & Mark A. Hall, *Private Equity and the Corporatization of Health Care*, 76 STAN. L. REV. 527, 543–46 (2024) (describing the private equity model of physician practice investment); Soleil Shah, Hayden Rooke-Ley & Erin C. Fuse Brown, *Corporate Investors in Primary Care — Profits, Progress, and Pitfalls*, 388 N ENGL J MED 99 (2023), <http://www.nejm.org/doi/10.1056/NEJMp2212841>.

the DTP model, by comparison, physicians may have even less clinical autonomy, fewer degrees of freedom, and a far narrower range of services they are expected to provide, which creates for the physicians near-total financial control and an insuperable conflict of interest.

B. Benefits of DTP Tele-Prescribing

DTP tele-prescribing arrangements have the potential to improve access, convenience, and reduce the costs for high-demand prescription drugs. Asynchronous care and affiliated pharmacies may offer faster access to treatment by eliminating insurance delays or the need to deal with potentially-overburdened local pharmacies. The arrangements may lower barriers to care for people with busy schedules, mobility issues, and those located in rural areas.⁴⁶ The press release announcing the launch of PfizerForAll argues that the platform makes it easier for patients to find co-pay cards and access Pfizer's affordability programs and patient support services.⁴⁷

Telehealth more broadly has been touted for its promise in providing greater access to health care services in rural and underserved areas.⁴⁸ One report concluded that in rural areas, telehealth usage resulted in a lower number of missed appointments and readmissions, shorter wait times, better adherence to medications, improved quality and timeliness of care, as well as reduced physician shortages by encouraging rural workforce recruitment and retention.⁴⁹ When used in the context of a traditional, long-term professional-

⁴⁶ Pat Carroll, *How Hims & Hers is Increasing Access to Care for Everyone*, HIMS & HERS NEWSROOM (July 8, 2024), <https://news.hims.com/newsroom/how-hims-hers-is-increasing-access-to-care-for-everyone>.

⁴⁷ *Pfizer Launches PfizerForAll™, a Digital Platform that Helps Simplify Access to Healthcare*, *supra* note 30.

⁴⁸ Maggie L. Shaw, *5 Specialty Care Shortages in Rural Communities*, AM. J. MANAGED CARE (Sep. 13, 2024), <https://www.ajmc.com/view/5-specialty-care-shortages-in-rural-communities>; Ryan Nestrick, *Bridging the Gap: Addressing Health Inequities in Rural Communities*, NAT'L RURAL HEALTH ASS'N (Sep. 20, 2024), <https://www.ruralhealth.us/blogs/2024/09/bridging-the-gap-addressing-health-inequities-in-rural-communities>.

⁴⁹ Michael Butzner & Yendelela Cuffee, *Telehealth Interventions and Outcomes Across Rural Communities in the United States: Narrative Review*, 23 J. MED. INTERNET

patient relationships, telehealth services produce similar outcomes as in-person care. For example, the effects of weight-loss treatment delivered via telemedicine and in-person visits were similar,⁵⁰ while another study found that substance use disorder patients appreciated “the implicit sense of autonomy and trust involved in being able to connect with clinicians through video or telephone visits.”⁵¹ DTP tele-prescribing may increase access to prescriptions for which there is unmet demand, whether due to supply shortages or long wait-times to see regular physicians, such as prescriptions for GLP-1 drugs to treat obesity-related health conditions.

A significant benefit of DTP tele-prescribing is that it provides access to drugs to treat stigmatized conditions, for which patients may be embarrassed to ask their regular physician or insurance may not cover. Indeed, DTP tele-prescribing companies commonly offer prescriptions for weight-loss, hair-loss, and sexual health, including erectile dysfunction.

DTP tele-prescribing could also provide cheaper prescriptions. Where an affiliated pharmacy is involved, the DTP tele-prescribing arrangement cuts out the middleman in many prescription drug purchases: the pharmacy benefit manager. The pharmacy benefit managers arrange drug benefits for health insurers by negotiating drug prices and rebates with drug manufacturers and contracting with participating pharmacies.⁵² Where a pharmaceutical manufacturer is involved, DTP tele-prescribing arrangements allow manufacturers, like Lilly or Pfizer, to sell their drugs directly to patients at discounted cash prices, thus eliminating the administrative hassle and associated costs of navigating insurance and prior authorization and coverage determinations by pharmacy benefit managers.⁵³ Yet, drug company copay

RSCH. e29575, at 2 (2021), [<https://doi.org/10.2196/29575>].

⁵⁰ Andrés R. Latorre-Rodríguez et al., *Adoption of Telemedicine for Obesity Treatment During the COVID-19 Pandemic Achieved Comparable Outcomes to In-Person Visits*, 12 OBES. PILLARS 100131, at 6 (2024), [<https://doi.org/10.1016/j.obpill.2024.100131>].

⁵¹ Oregon Health & Science University, *Telehealth Reduces Stigma and Barriers for Addiction Treatment, Study Finds*, NEWS MED. (July 8, 2024), <https://www.news-medical.net/news/20240708/Telehealth-reduces-stigma-and-barriers-for-addiction-treatment-study-finds.aspx>.

⁵² T. Joseph Mattingly II, David A. Hyman & Ge Bai, *Pharmacy Benefit Managers: History, Business Practices, Economics, and Policy*, 4 JAMA HEALTH F. e233804 (2023), [<https://doi.org/10.1001/jamahealthforum.2023.3804>].

⁵³ Benjamin N. Rome, *Direct-to-Consumer Drug Company Pharmacies*, 331 JAMA 1003, 1003 (2024), [<https://doi.org/10.1001/jama.2024.2911>].

coupons and discounts offered through these channels may not actually reduce a patient's prescription drug costs, particularly if they are directed to cheaper alternatives or pay cash for drugs that insurance may have covered.⁵⁴ Thus, the promise of cheaper drugs may be somewhat illusory or provide only marginal savings in the face of rising drug prices.

C. Concerns about the Direct-to-Prescription Model

The increase in use of the DTP Model, particularly where pharmaceutical manufacturers are directly involved, has also prompted concerns among policymakers and observers.⁵⁵ The concerns relate to patient safety, health spending, and erosion of the physician-patient relationship. The patient safety concerns stem from the risks that the cursory evaluations and financial incentives may lead to inappropriate prescriptions and inadequate clinical screening and follow-up care in the event of adverse reactions. Health spending may be driven unnecessarily higher by overuse of expensive drugs, which may, in some cases, result in fraudulent claims to federal health care programs. Further, these arrangements may commercialize the physician-patient relationship, undermine trust in the profession, and fragment care, which may ultimately burden the patient's regular source of care to manage drug interactions or contraindications, as the DTP provider may not address those issues.

For years, the Office of Inspector General of the Department of Health and Human Services (HHS-OIG) has warned of the risk of health care fraud and patient steering from pharmaceutical manufacturers' financial incentives to prescribing physicians as well as telehealth companies' relationships with clinicians.⁵⁶ The emergence of DTP tele-prescribing combines and amplifies

⁵⁴ *Id.*

⁵⁵ Adriane Fugh-Berman & Judy Butler, *Pharma's Ethically Questionable Sites Essentially Sell Drugs Directly to Consumers*, STAT (Nov. 6, 2024), <https://www.statnews.com/2024/11/06/lilly-pfizerforall-amgen-abbvie-direct-consumer-sales-paxlovid-migraine-drugs/>; Katie Palmer, *Senators Demand Answers on Telehealth Platforms from Pfizer and Eli Lilly*, STAT (Oct. 22, 2024), <https://www.statnews.com/2024/10/22/senators-letter-pfizer-eli-lilly-ceos-telehealth-prescription/>.

⁵⁶ U.S. DEP'T OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., 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> [hereinafter HHS-OIG SPECIAL FRAUD ALERT]; U.S. DEP'T OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., SPECIAL

these financial conflicts of interest inherent in both these types of financial arrangements, especially when they involve all three entities: the pharmaceutical manufacturer, the telehealth company, and the prescribing clinician, who all stand to make money for prescriptions ordered via this integrated platform. The Department of Justice (DOJ) has also targeted fraud schemes involving telehealth and marketing companies that enforcers say contribute to public distrust in medical institutions,⁵⁷ threaten the safety of patients and the integrity of health care programs,⁵⁸ and increase taxpayers' burden from premiums and out-of-pocket expenses.⁵⁹

The overprescription of branded drugs and the associated growth in overall health care costs is a major concern surrounding the DTP Model. Senators Dick Durbin (D-IL), Bernie Sanders (I-VT), Elizabeth Warren (D-MA), and Peter Welch (D-VT) issued a report in 2025 following an investigation into pharmaceutical-telehealth partnerships by Eli Lilly and Pfizer.⁶⁰ The Senators' report stated that these novel arrangements "appear intended to steer patients toward particular medications. At best, these relationships raise questions about conflicts of interest. At worst, they create the potential for inappropriate prescribing that can unnecessarily increase spending for federal health care programs."⁶¹ The report found that 74% of patients who were routed to a telehealth partner by LillyDirect received a prescription for a Lilly medication, and 85% of patients routed by Pfizer to

FRAUD ALERT: SPEAKER PROGRAMS (Nov. 16, 2022), <https://oig.hhs.gov/documents/special-fraud-alerts/865/SpecialFraudAlertSpeakerPrograms.pdf>.

⁵⁷ *Federal Law Enforcement Action Involving Fraudulent Genetic Testing Results in Charges Against 35 Individuals Responsible for over \$2.1 Billion in Losses in One of the Largest Health Care Fraud Schemes Ever Charged*, U.S. DEP'T OF JUST., OFF. OF PUB. AFFS. (Sep. 27, 2019), <https://www.justice.gov/archives/opa/pr/federal-law-enforcement-action-involving-fraudulent-genetic-testing-results-charges-against>.

⁵⁸ *2020 National Health Care Fraud and Opioid Takedown*, U.S. DEP'T OF JUST., CRIM. DIV. (Aug. 11, 2023), <https://www.justice.gov/criminal/criminal-fraud/hcf-2020-takedown/press-release>.

⁵⁹ *Federal Indictments & Law Enforcement Actions in One of the Largest Health Care Fraud Schemes Involving Telemedicine and Durable Medical Equipment Marketing Executives Results in Charges Against 24 Individuals Responsible for over \$1.2 Billion in Losses*, U.S. DEP'T OF JUST., OFF. OF PUB. AFFS. (Apr. 9, 2019), <https://www.justice.gov/archives/opa/pr/federal-indictments-and-law-enforcement-actions-one-largest-health-care-fraud-schemes>.

⁶⁰ DURBIN ET AL., *supra* note 10, at 1.

⁶¹ *Id.*

its telehealth partner received a prescription.⁶² While it is difficult to ascertain whether these prescribing practices differ systematically from the prescribing rates by unaffiliated telehealth or traditional providers, it suggests that the platform is, not surprisingly, very effective at converting patient interest into prescriptions. These financial relationships raise concerns of patient steering and inappropriate prescribing, which threatens to worsen patient care and increase health spending on unnecessary drugs.

The absence of personalized engagement can negatively impact physician-patient relationships, making care more transactional than relational. The relationship between a doctor and a patient is characterized by knowledge asymmetry—patients trust the doctor to act in their best interest, to share information and advice about their medical conditions that they lack, and provide services that are accurate, comprehensive, and competent.⁶³ This requires physicians to build empathy by spending sufficient time with patients, allowing them to understand patients' perspectives and emotions.⁶⁴ Higher levels of physician empathy can improve health outcomes by enhancing communication. As patients become more open and honest about their needs, physicians can make more accurate and appropriate diagnoses and treatment options, resulting in increased patient satisfaction and compliance with care decisions.⁶⁵ Patients value physicians' interpersonal skills, especially since it can be difficult to judge them for their technical proficiency.⁶⁶

Such robust, trust-based relationships are much rarer on telehealth platforms. By employing a medication-first approach—where patients consult a provider after self-diagnosing their symptoms and selecting specific drugs they want, and physicians exist primarily to authorize a prescription rather than to explore various treatment options—the use of DTC marketing

⁶² *Id.* at 10.

⁶³ Claudia E. Haupt, *The Professional Regulation and Ethics of Direct-to-Prescription Marketing*, AM. J.L. & MED. (forthcoming 2026). [<https://doi.org/10.2139/ssrn.5381960>].

⁶⁴ Qing Wu, Zheyu Jin & Pei Wang, *The Relationship Between the Physician-Patient Relationship, Physician Empathy, and Patient Trust*, 37 J. GEN. INTERN. MED. 1388, 1389 (2022), [<https://doi.org/10.1007/s11606-021-07008-9>].

⁶⁵ Bhautesh Dinesh Jani; David N. Blane & Stewart W. Mercer, *The Role of Empathy in Therapy and the Physician-Patient Relationship*, 19 RSCH. COMPLEMENTARY MED. 252, 253–54 (2012), [<https://doi.org/10.1159/000342998>].

⁶⁶ Neeli M. Bendapudi et al., *Patients' Perspectives on Ideal Physician Behaviors*, 81 MAYO CLIN. PROC. 338, 341 (2006), [<https://doi.org/10.4065/81.3.338>].

eliminates a period of trial and error that comes with traditional visits to a doctor's office, creating a risk of substandard care.⁶⁷ The fact that many of these platforms do not offer or require real-time, synchronous video appointments and rely heavily on independent physicians brought on through short-term contracts exacerbates the problem, as patients are unable to build long-term rapport with providers "with a vested interest in improving their health."⁶⁸

For example, a recent survey on GLP-1 weight loss medications conducted by Omada Health, a San Francisco health care consultancy, found that the majority of the 2,000 primary care physician respondents were concerned about safety risks associated with accessing GLP-1 via third-party telehealth providers.⁶⁹ The respondents highlighted that third-party prescriptions can compromise continuity of care, and that the lack of transparency between virtual providers and primary care physicians can make it challenging to support each patient's treatment journey by addressing side effects and providing emotional and lifestyle assistance.⁷⁰

Compensation structures employed by telehealth platforms are another factor that can contribute to substandard care, as they provide considerable income potential, motivating physicians to see as many patients as possible. There are three common compensation structures used by telehealth platforms to compensate providers: a flat rate per consultation, where physicians are paid a pre-determined amount for each consultation regardless of its length; an hourly rate for services provided, where physicians can perform multiple consultations within the hours paid; and a stipend for availability, where physicians are compensated additionally for the burden

⁶⁷ Katie Palmer, *To Help Migraine Patients — and Sell More Medicines — Major Drugmakers Turn to Telehealth*, STAT (Aug. 27, 2024), <https://www.statnews.com/2024/08/27/migraine-medication-direct-to-consumer-pharma-telehealth-portal-pfizer-for-all/>.

⁶⁸ DURBIN ET AL., *supra* note 10, at 6.

⁶⁹ OMADA, SURVEY REPORT: PRIMARY CARE PERSPECTIVES ON GLP-1 PRESCRIPTIONS 2, 5 (2025), <https://www.omadahealth.com/resource-center/survey-report-primary-care-perspectives-on-glp-1-prescriptions>.

⁷⁰ *Id.* at 6; see also Meena Ramachandran et al., *The Impact of eHealth on Relationships and Trust in Primary Care: A Review of Reviews*, 24 BMC PRIM. CARE 1 (2023), [<https://doi.org/10.1186/s12875-023-02176-5>]; K.R. Jongsma et al., *How Digital Health Affects the Patient-Physician Relationship: An Empirical-Ethics Study into the Perspectives and Experiences in Obstetric Care*, 25 PREGNANCY HYPERTENS. 81 (2021), [<https://doi.org/10.1016/j.preghy.2021.05.017>].

they assume for choosing to be available for a particular period.⁷¹

Whenever there is the potential that physicians are writing prescriptions without adequate care and evaluation—a substantial concern of the DTP telehealth model—there is the risk of harm from inappropriate prescribing. It is probably not a coincidence that dramatic growth and visibility of the DTP Model has been driven by products without highly publicized safety concerns. GLP-1 medications, for example, have been portrayed in the media as “miracle” drugs with the ability to not only reduce weight and diabetes but also heart attacks and strokes and even addiction.⁷² There has been comparatively little media coverage of potential safety concerns surrounding the drugs.⁷³ It is beyond the scope of this article to

⁷¹ Carol Carden & Zach Doolin, *Health Care Operations & Compliance, Professional Perspective - An Introduction to Valuing Telemedicine Services*, BLOOMBERG L. (Sep. 2017), <https://www.bloomberglaw.com/external/document/X2B11EP4000000/health-care-operations-compliance-professional-perspective-an-in>.

⁷² See, e.g., Gary Winslett, ‘Ozempic for All’ is Starting to Make Economic Sense, WASH. POST (Aug. 21, 2025), <https://www.washingtonpost.com/opinions/2025/08/21/ozempic-for-all-glp-1/>; Sara Reardon, *How ‘Miracle’ Weight-Loss Drugs Will Change the World*, NATURE (Nov. 5, 2024), <https://www.nature.com/articles/d41586-024-03589-7>; Amandeep S. Grewal, *It’s Magic?: Ozempic, Addiction Treatment, and the Law*, 36 HEALTH MATRIX (Mar. 2026), [<https://dx.doi.org/10.2139/ssrn.5322092>].

⁷³ See Katie Palmer, *The Virtual Rx Boom: From Erectile Dysfunction to Weight Loss, How Telehealth Got Hooked on Drug-First Thinking*, STAT (Oct. 6, 2025), <https://www.statnews.com/2025/10/06/telehealth-companies-shift-from-providing-patient-access-to-selling-drugs/> (noting that for drugs to work in the direct-to-consumer telehealth prescribing model, they “had to be low-risk enough that a physician could safely prescribe it without a physical exam or blood tests”).

That is not to say there have been no complaints of patient harm from GLP-1 medications. For example, former patients have sued Novo Nordisk alleging they suffered permanent vision loss after taking Ozempic and Wegovy. See Request for Multicounty Designation of NAION Ozempic/Wegovy Litigation at 2 (June 12, 2025), <https://www.njcourts.gov/sites/default/files/mcl/ozempic-wegovy/application-naion-ozempic-wegovy-litigation.pdf>.

There have also been reports of patients being hospitalized after lying about their weight on telehealth platforms in order to obtain the medications. Kate Bowie, ‘It Terrifies Me’: Girl Landed in A&E After Buying Wegovy from Boots, CHEMIST+DRUGGIST (June 12, 2024), <https://www.chemistanddruggist.co.uk/CD138263/It-terrifies-me-Girl-landed-in-AE-after-buying-Wegovy-from-Boots>. The authors went through the process of attempting to obtain a GLP-1 medication through Hers and Ro. On both Hers and Ro, the authors were able to repeatedly go back and change the weight of a prospective patient until it was high

address whether the Food and Drug Administration should be characterizing more drugs as over the counter (OTC) rather than requiring a prescription, or whether the Food and Drug Administration should consider a third category of over-the-counter-plus medications—requiring the sign-off of a physician but with a lesser expectation of review than that assigned to prescription medications. As currently designed, the Food and Drug Administration’s approval of a drug requiring a prescription assumes a true doctor-patient relationship and a meaningful review by the prescribing physician. Inherent in that system is thus the assumption that if the Food and Drug Administration has required a prescription, there is a risk of patient harm if patients can obtain the medication without a true doctor-patient relationship and a meaningful review by the prescribing physician.

While some may tout the DTP Model as providing greater access to prescription drugs on demand, the Model’s growth may commercialize the physician-patient relationship and normalize a pay-for-prescription transactional experience that is divorced from ongoing care relationships. This could fragment the patient’s health care and burden the patient’s usual source of care, such as their primary care provider, with piecing together the patient’s medication history and managing unanticipated adverse events and drug interactions. Further, reducing what is traditionally a fiduciary and trust-based relationship to a commercial transaction could erode trust in the medical profession and undermine the clinician’s sense of professionalism and the quality of the care.

II. LEGAL TOOLS TO ADDRESS RISKS OF THE DTP ARRANGEMENTS

A. *Direct-to-Prescription Models are Difficult Targets for Anti-Kickback Statute-based Enforcement*

The Department of Justice and Health & Human Services-OIG have identified the Anti-Kickback Statute as the potential enforcement tool to address inappropriate arrangements between physicians and telemedicine companies. Despite the theoretical and rhetorical fit between the Anti-Kickback Statute and the risks of DTP arrangements, actual violations may

enough to qualify for the medication. Neither system had in place a mechanism of identifying the changed entry and questioning the patient’s information.

be more difficult to prove in practice.⁷⁴ Anti-Kickback Statute Analysis of the Anti-Kickback Statute and various DTP arrangements explains why there have been no public government enforcement actions despite entities paying physicians to mass produce prescriptions for pre-selected drugs. This analysis also explains why telehealth companies, and even drug manufacturers, are likely to become increasingly comfortable with DTP arrangements, which offer manufacturers a powerful way to grow their business.

HHS-OIG's decision to issue a Special Fraud Alert on the risks of telemedicine arrangements under the Anti-Kickback Statute signals that DTP models would be subject to scrutiny. Thus, even in the absence of successful prosecution, the Anti-Kickback Statute has likely shaped how these arrangements have been structured. HHS-OIG's July, 20, 2022, Special Fraud Alert states telemedicine "schemes . . . may implicate multiple federal laws."⁷⁵ The focus is on the Anti-Kickback Statute, and the reference to "multiple" laws is primarily based on statutes derivative of the Anti-Kickback Statute ("OIG's exclusion authority related to kickbacks, the Civil Monetary Penalties Law provision for kickbacks . . . and the False Claims Act"), where the statutes would not be applicable if there were not first an Anti-Kickback Statute violation. Section 1128(b)(7), 1128(a)(7), 31 U.S.C. §§ 3729-33. The only exception is the Alert's reference to the criminal health care fraud statute (18 U.S.C. § 1347), which would require the government to prove the prescriptions were medically unnecessary.⁷⁶

The Anti-Kickback Statute prohibits paying or receiving anything of value in order to induce referrals or recommendations for any items or services paid for by a federal health care program.⁷⁷ For some entities, analysis of the legality of DTP arrangements under the Anti-Kickback Statute has largely ended there—many well-publicized programs have thus far avoided federal insurance programs, removing any potential Anti-Kickback Statute applicability.⁷⁸ The Hims & Hers website, for example, notes that the entity is "not enrolled with, and are not participating providers with, any federal or state health care programs (i.e., Medicare, Medicaid) . . . By choosing to use the Service, you are specifically choosing to obtain products

⁷⁴ See Fuse Brown, Wouters, Mehrotra, *supra* note ___, at 1149 (Noting that "[t]he key law governing these relationships in the United States is the Anti-Kickback Statute").

⁷⁵ HHS-OIG SPECIAL FRAUD ALERT, *supra* note 56.

⁷⁶ *Id.*

⁷⁷ 42 U.S.C. § 1320a-7b.

⁷⁸ Onder & Sinha, *supra* note 28.

and services on a cash basis outside of any federal or state health care program.”⁷⁹

But this is not to say the entities are engaged in conduct that would trigger Anti-Kickback Statute-based enforcement if government programs were involved. Entities such as Form Health (a telehealth company partnered with Eli Lilly to provide obesity care, including prescribing of Eli Lilly’s weight loss drug, Zepbound), do participate in Medicare, seemingly confident they have developed structures that will avoid the Anti-Kickback Statute’s other requirements.⁸⁰ While the HHS-OIG Special Fraud Alert states that relationships between physicians and telemedicine companies may raise “a heightened risk of fraud and abuse,” the Anti-Kickback Statute’s elements create significant challenges for enforcers. As a result, while many telehealth entities have shied away from participation in government health care programs, as DTP arrangements grow in acceptance and use, it is inevitable even companies that have avoided government programs will seek to expand into federal insurance, trusting their structures will avoid Anti-Kickback Statute’s other elements.

In particular, the statute’s “to induce” language and *mens rea* requirement significantly narrow the statute’s reach, creating a sizeable hurdle to efforts by enforcers to use the Anti-Kickback Statute to limit the proliferation of direct-to-prescribing arrangements.

The Anti-Kickback Statute does not categorically bar even direct payments between a pharmaceutical company and a physician who may prescribe the company’s products. The Anti-Kickback Statute instead only prohibits offering, paying, soliciting, or receiving anything of value to induce or reward referrals or generate federal health care program business.⁸¹ Notably, liability under the Anti-Kickback Statute ultimately requires proof of a party’s intent. The mere fact that remuneration is provided to a health care provider does not make it a kickback. The statute forbids only remuneration provided “in return for” or “to induce” prescribing.⁸² If

⁷⁹ *Terms and Conditions*, HIMS & HERS, <https://www.hims.com/terms-and-conditions> (last visited Jan. 25, 2026).

⁸⁰ *Frequently Asked Questions*, FORM HEALTH, <https://www.formhealth.co/faqs> [<https://perma.cc/B9S9-EDTY>] (last visited Sep. 4, 2025); *Independent Telehealth for Obesity*, LILLY, <https://www.lilly.com/find-care/telehealth/obesity> [<https://perma.cc/YC26-C2YA>] (last visited Sep 4, 2025).

⁸¹ 42 U.S.C. § 1320a-7b.

⁸² 42 U.S.C. § 1320a-7b(1) and (2). The Anti-Kickback Statute also includes a

payments are made for another purpose, they do not violate the Anti-Kickback Statute. Circuit Courts split on whether the statute would be violated if “one purpose” of the payment were to induce referrals or if the statute is only violated if inducing the prescription were the “primary purpose” of the payment.⁸³ Under any reading, however, there is no violation if the payments are entirely for another purpose, and a lawful payment does not become unlawful solely because the payee expects the result will be increased prescribing by the paid physician. An enforcer bringing an Anti-Kickback Statute case will need to prove the money was paid to induce, or the enforcement action will fail.

The following hypotheticals illustrate the distinction: If a telehealth company pays a physician in exchange for writing a prescription, the inducement element of the Anti-Kickback Statute will be satisfied. If instead, however, the telehealth company pays the physician not for writing a prescription, but solely for conducting a patient evaluation, it may be harder to prove that such a payment constituted an inducement. Much would depend on how much discretion the physician had, what other financial incentives they faced, whether prescription patterns changed, and other facts that are more difficult to prove.⁸⁴ It would be harder to establish that the telehealth company’s payments were intended to induce a prescription from the patient evaluation—it is plausible the purpose of the payment was solely in exchange for conducting the patient evaluation and not to reward or induce the prescription. The same analysis holds if the payments are between a pharmaceutical manufacturer and a physician or a between a pharmaceutical manufacturer and a telehealth entity, which in turn enters into an arrangement with physicians—if the payments are solely in exchange for conducting patient evaluations, the element of inducement may be more difficult to prove.

Financial relationships may be further insulated from enforcement if

separate *mens rea* requirement that the defendant act “willfully,” meaning with knowledge that their conduct was unlawful, even if they do not have actual knowledge of the Anti-Kickback Statute or specific intent to commit a violation of the Anti-Kickback Statute. 42 U.S.C. § 1320a-7b(h).

⁸³ Compare *United States v. Greber*, 760 F.2d 68, 69 (3d Cir. 1985) (one purpose), with *United States v. Bay State Ambulance & Hosp. Rental Serv.*, 874 F.2d 20, 30 (1st Cir. 1989) (primary purpose).

⁸⁴ See *Fuse Brown, Wouters, Mehrotra*, *supra* note ___, at 1149-50 (describing facts and factors that might help determine whether an Anti-Kickback Statute violation occurred despite the lack of direct payment in exchange for prescriptions).

they meet one of several safe harbors. Left alone, the Anti-Kickback Statute's basic prohibitions could prohibit business arrangements viewed by Congress as innocuous or even beneficial to the health-care system. This prohibition would include arrangements in which pharmaceutical and device manufacturers pay physicians to share their expertise either as consultants to the manufacturer or as speakers to educate other doctors. Therefore, to soften the Anti-Kickback Statute's broad reach, Congress enacted a provision requiring the development and promulgation of safe harbors.⁸⁵ The safe harbors "specify various payment and business practices that [are not] subject to sanctions under the anti-kickback statute, even though they potentially may be capable of inducing referrals" of federal health-care program business.⁸⁶ Included amongst the safe harbors is one for "[p]ersonal services and management contracts," which permits, amongst other things, payments from manufacturers to physicians for work as consultants or speakers as long as certain conditions are met, including the payments being fair market value.⁸⁷ The safe harbors exist because, from the perspective of the government as payor, the benefits of certain relationships between physicians and manufacturers outweigh the risk that the relationships will influence physician decision-making regarding prescribing or use of medical devices.

Considering potential DTP arrangements, they may be structured in ways that make Anti-Kickback Statute-based enforcement prohibitively difficult. For example, a telehealth company may hire physicians to evaluate patients' information and their requests for prescriptions. If the telehealth company pays the physicians on a per-prescription basis, or tells them they are expected to write the requested prescriptions in order to be paid, an enforcer will have little difficulty establishing the payments are "to induce" prescribing and violate the Anti-Kickback Statute. But entities can structure relationships without running afoul of the Anti-Kickback Statute—or at least making enforcement more difficult—while yielding the same results. If instead of paying reviewing physicians per prescription, the telehealth company pays the physicians for the evaluations and pays the physicians only an amount representing fair-market value for a patient evaluation, the

⁸⁵ See Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, § 14(a), 101 Stat. 680, 697 (1987); 42 U.S.C. § 1320a-7b(b)(3)(E).

⁸⁶ Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 85 Fed. Reg. 77684, 77687 (Dec. 2, 2020) (codified at 42 C.F.R. pts. 1001, 1003).

⁸⁷ 42 C.F.R. § 1001.952(d) (2022).

relationship likely avoids satisfying the Anti-Kickback Statute’s “to induce” requirement—the payments would be for the evaluation, not the prescription—unless an enforcer can establish the true intent was to induce prescriptions. An entity may take a number of steps to avoid violating the Anti-Kickback Statute, or at least make enforcement prohibitively difficult, including making clear through their financial relationship and documented training that payments are not contingent upon the writing of prescriptions. If the relationships are set up to meet the requirements, they may even satisfy the personal services safe harbor (including having a term of at least one year), giving even more comfort to the involved parties.⁸⁸ An active compliance program monitoring physician activity to confirm they are devoting a reasonable amount of time to each evaluation and not quickly rubber-stamping requests would create an additional enforcement hurdle.

Similarly, a pharmaceutical company paying a telehealth entity for providing access for interested patients to physicians for evaluations may create substantial enforcement hurdles by structuring the arrangement as a flat-fee and making clear the payments are for evaluations rather than prescriptions. An enforcer would need to establish the payment is intended to induce prescriptions to satisfy the inducement element—it would not be enough to prove the pharmaceutical manufacturer hopes and expects prescriptions will result from the arrangement.

Even were a pharmaceutical manufacturer contracting directly with physicians rather than a telehealth company in between, similar structures can be designed to create substantial challenges for any enforcer seeking to use the Anti-Kickback Statute to rein in the practice. Again, the agreements would need to make clear the physicians are being paid for the evaluations regardless of whether they write the requested prescriptions. The physicians could plausibly say they did not feel required to write prescriptions and were always instructed to exercise their independent medical judgment, and the non-secretive nature of the relationship (formal contracts prepared and reviewed by attorneys on both sides) would belie any suggestion the parties

⁸⁸ 42 C.F.R. § 1001.952(d) (2022). Even if the arrangement fails to satisfy the personal services safe harbor, there will only be a violation of the Anti-Kickback Statute if all elements are met. As long as the payments are for the evaluation and not to write a prescription, there will still be no violation of the Anti-Kickback Statute.

A recent HHS-OIG Advisory Opinion found that a telehealth platform-clinician arrangement structured to fit within the management services safe harbor, 42 C.F.R. § 1001.952(d)(1), can avoid leading to improper remuneration under the AKS. U.S. Dep’t of Health & Hum. Servs., Off. of Inspector Gen., *supra* note 26. Although the arrangement discussed differs in significant respects from those involving pharmaceutical manufacturers, it demonstrates the protection offered by the AKS safe harbors to sophisticated entities.

were willfully violating the law (the Anti-Kickback Statute’s additional *mens rea* requirement). But is there any doubt a physician in that situation would understand they are there to write prescriptions and the telehealth company or manufacturer expects them to do so? The relationship represents a weak spot in the Anti-Kickback Statute where the statute’s *mens rea* requirements—intentionally in place to avoid criminalizing beneficial relationships—protect conduct lacking systemic benefits. Physicians and customers in those situations would have no real doctor-patient relationship before, during, or after the evaluation, and the physician is unlikely to do any greater evaluation or counseling than can be done through a series of online multiple-choice questions.⁸⁹

To be clear, it is not difficult to imagine any and all of the above potential relationships running afoul of the Anti-Kickback Statute where there is sufficient evidence of an intent to induce—having contractual terms which on their face avoid inducement does not automatically render an arrangement lawful. Payments need not be “per prescription” or “for a pre-determined volume” to violate the Anti-Kickback Statute, and it is unclear why a pharmaceutical manufacturer would want to financially support a telehealth platform other than to promote prescriptions. As a result, a pharmaceutical manufacturer entering into a relationship with a telehealth platform creates enforcement risk for all parties. The 2025 Senate Report’s suggestion that these relationships may be problematic under the Anti-Kickback Statute may alone push pharmaceutical manufacturers and telehealth platforms to shy away from those specific arrangements to reduce enforcement risk.

Available information surrounding pharmaceutical manufacturers’ recent arrangements with telehealth companies to evaluate patients for potential use of the manufacturers’ drugs, however, illustrates both the ways in which the arrangements may contribute to the degradation of the physician-patient relationship and the inadequacy of the Anti-Kickback Statute to address concerns regarding the arrangements.

The 2025 Senate Report found Eli Lilly and Pfizer have paid hundreds of thousands of dollars to telehealth platforms.⁹⁰ As detailed above, the pharmaceutical companies have used DTC advertising to promote their drugs, and then directed interested patients to telehealth platforms where

⁸⁹ It is through use of such questions that entities have been able to ensure they are only paying physicians to “evaluate” patients for whom they will agree to write the requested prescription.

⁹⁰ DURBIN ET AL., *supra* note 10, at 8.

prescribers have written large numbers of prescriptions for the manufacturers' drugs. The relationships raise the concerns detailed in Part I.C., above, as the patients are directed to physicians with whom they have no prior, and likely no future, relationship, and the physicians are aware they are dealing with a request for a specific drug from the patient. The evaluations are not even necessarily over video, and are of limited duration.⁹¹

Yet there is reason for skepticism that the 2025 Senate Report's seeming reliance on the Anti-Kickback Statute to address the relationship is well-placed. Notably, what is known of the arrangements does seem designed to avoid some of the "list of suspect characteristics" identified by HHS-OIG in its Special Fraud Alert focused on relationships between telehealth entities and physicians. Analysis of other "suspect characteristics" reveals their presence does not necessarily mean an enforcer will be able to establish payments were intended to induce and thus violate the Anti-Kickback Statute.

The HHS-OIG Special Fraud Alert lists six "suspect characteristics," which HHS-OIG states "[b]ased on OIG's and DOJ's enforcement experience . . . taken together or separately, could suggest an arrangement that presents a heightened risk of fraud and abuse.":

- 1) The purported patients for whom the Practitioner orders or prescribes items or services were identified or recruited by the Telemedicine Company, telemarketing company, sales agent, recruiter, call center, health fair, and/or through internet, television, or social media advertising for free or low out-of-pocket cost items or services.
- 2) The Practitioner does not have sufficient contact with or information from the purported patient to meaningfully assess the medical necessity of the items or services ordered or prescribed.
- 3) The Telemedicine Company compensates the Practitioner based on the volume of items or services ordered or prescribed, which may be characterized to the Practitioner as compensation based on the number of purported medical records that the Practitioner reviewed.
- 4) The Telemedicine Company only furnishes items and services to Federal health care program beneficiaries and does not accept insurance from any other payor.

⁹¹ *Id.* at 4.

- 5) The Telemedicine Company claims to only furnish items and services to individuals who are not Federal health care program beneficiaries but may in fact bill Federal health care programs.
- 6) The Telemedicine Company only furnishes one product or a single class of products (e.g., durable medical equipment, genetic testing, diabetic supplies, or various prescription creams), potentially restricting a Practitioner's treating options to a predetermined course of treatment.⁹²

HHS-OIG does not suggest any of these characteristics are dispositive of a legal violation, noting “[t]his list is illustrative, not exhaustive, and the presence or absence of any one of these factors is not determinative of whether a particular arrangement with a Telemedicine Company would be grounds for legal sanctions.”⁹³ Still, it is notable that the arrangements described in the Senate Report likely avoid several of these characteristics, and others would not be, without more, the basis for an Anti-Kickback Statute violation.

The arrangements described in the Senate Report do not appear to feature characteristics 3, 4 or 5. The manufacturers and telehealth platforms reported to the Senate investigation that the manufacturers “are not paying incentives or bonuses per prescription or contracting for a pre-determined volume.”⁹⁴ This structure was presumably created to avoid running afoul of

⁹² HHS-OIG SPECIAL FRAUD ALERT, *supra* note 56, at 4–5. (The Special Fraud Alert used bullet points rather than numbering. Numbering has been inserted here for ease of reference.)

Notably, while the 2022 Special Fraud Alert takes for granted that physicians writing prescriptions filled by telemedicine companies will be employed by those telemedicine companies, a separate HHS-OIG Special Advisory Bulletin issued in January 2026 suggests the connection itself is cause for concern. U.S. DEP’T OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., SPECIAL FRAUD 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), <https://oig.hhs.gov/documents/special-advisory-bulletins/11450/OIG--FINAL--Special-Advisory-Bulletin.pdf>. The 2026 Special Advisory Bulletin focuses on programs allowing patients to fill separately-obtained prescriptions through platforms connected to pharmaceutical companies. In noting the characteristics that would “minimize the risk of fraud and abuse under the [Anti-Kickback Statute],” the first characteristic listed is that “[t]he individual has a valid prescription from an independent, third-party prescriber”—exactly what is missing in DTP arrangements. *Id.*

⁹³ *Id.* at 4.

⁹⁴ DURBIN ET AL., *supra* note 10, at 8.

the Anti-Kickback Statute.⁹⁵ As noted above, this may be a distinction without a difference, as a physician hired by such an entity would likely understand they are expected to write the prescriptions requested by the patients. This is especially true when considering the websites utilize online questionnaires to pre-screen patients for their suitability for the desired drug before connecting the patient with the physician, but the suspect characteristics are still not present.

Suspect characteristic 2 addresses situations where the physician “does not have sufficient contact with or information from the purported patient to meaningfully assess the medical necessity of the items or services ordered or prescribed.”⁹⁶ Here again, the entities have seemingly designed the online questionnaires and pre-screening to address this concern. Given the subjective nature of the practice of medicine and medical necessity determinations, it would be difficult for an enforcer to argue this characteristic is present. This characteristic relates to, but is notably different from, the concern expressed in the Senate Report and elsewhere that “for most of the telehealth arrangements, it is not a requirement for the clinician to obtain every patient’s underlying medical records.”⁹⁷ It is likely not a coincidence HHS-OIG took a less restrictive approach on this issue, as it is commonplace in today’s health care delivery system for in-person doctors to write prescriptions without obtaining prior medical records.

Suspect characteristics 1 and 6 seem closest to being present in DTP arrangements, but are unlikely to provide a sufficient basis for the government to proceed with an enforcement action. While patients may come to the telehealth entities as a result of “internet, television, or social media advertising for . . . low out-of-pocket cost items,” (suspect characteristic 1) that alone does not create a violation of the Anti-Kickback Statute. The same can be said for the arrangements focused only on “one product or a single class of products” (suspect characteristic 6). These suspect characteristics are seemingly based on instances where patients were misled and lured into providing billing information, with physicians then used to “rubber stamp” unnecessary prescriptions, rather than the arrangements referenced in the Senate Report, in which patients are actively seeking a specific medication.⁹⁸

⁹⁵ It is unclear whether any arrangements with this structure implicate government health care programs. Some telehealth platforms, such as Hims & Hers, do not accept insurance. Others, including Form Health, are covered by Medicare. *Id.* at 13.

⁹⁶ HHS-OIG SPECIAL FRAUD ALERT, *supra* note 56, at 4–5.

⁹⁷ DURBIN ET AL., *supra* note 10, at 6.

⁹⁸ *Operation Rubber Stamp: Major Health Care Fraud Investigation Results in*

These characteristics are potentially aimed more towards fraud than violations of the Anti-Kickback Statute, likely requiring an enforcement action to establish the prescriptions were not medically appropriate—a high bar, especially with the use of online questionnaires and pre-screening.

What is more, manufacturers and telehealth platforms may be able to largely achieve the same ends through structures with even less enforcement risk, potentially fueling growth of the practice. For example, if a telehealth platform is designed to make it easy for patients to obtain a prescription, pharmaceutical manufacturers may elect to direct patients to those platforms knowing it will facilitate prescriptions, even without any arrangement between the manufacturer and the platform. This would seemingly be little different from the common practice of medical device manufacturers including on their websites a “Physician Locator Service” to “[m]ake it easy for patients and other medical professionals to find information about . . . practitioners who treat specific medical conditions with [the specific manufacturer’s] products.”⁹⁹ As long as the manufacturers use past product usage to determine inclusion in their listings and avoid promoting the listings to physicians as an inducement to continue using the manufacturer’s products, any potential enforcement action would face substantial hurdles. There, the relationship may be purely symbiotic—physicians benefit from the referrals and the manufacturers benefit by being able to direct patients to physicians they can expect will use their products. In the case of telehealth platforms, the telehealth platform would benefit from the referrals, and the pharmaceutical manufacturers would benefit from being able to direct patients to physicians who they can expect will provide the requested prescriptions and drugs. It is inevitable under this structure the telehealth platforms will understand the referrals will stop if patient prescription

Significant New Charges, U.S. ATT’Y’S OFF., S.D. GA. (Oct. 7, 2020), <https://www.justice.gov/usao-sdga/pr/operation-rubber-stamp-major-health-care-fraud-investigation-results-significant-new> [<https://perma.cc/YZS8-5D4Y>]; *see also Alabama Doctor Charged with \$6 Million Telemedicine Health Care Fraud Scheme*, U.S. ATT’Y’S OFF., D. MASS. (Aug. 18, 2025), <https://www.justice.gov/usao-ma/pr/alabama-doctor-charged-6-million-telemedicine-health-care-fraud-scheme> [<https://perma.cc/FE24-95WS>]; *Ohio Doctor Pleads Guilty to Role in Telemedicine Scheme*, U.S. ATT’Y’S OFF., N.D. OHIO (July 10, 2025), <https://www.justice.gov/usao-ndoh/pr/ohio-doctor-pleads-guilty-role-telemedicine-scheme> [<https://perma.cc/FV4L-3JZM>].

⁹⁹ *Physician Locator Service*, DEPUY SYNTHES, <https://www.jnjmedtech.com/en-US/treatment/physician-locator-services> (last visited Jan. 25, 2026); *see also Physician Locator*, STRYKER: INTERVENTIONAL SPINE, <https://strykerivs.com/physician-locator> [<https://perma.cc/RD9T-M4ZN>] (last visited July 22, 2025) (providing a website where patients can “[c]lick on [their] state or enter [their] zip code to find the physician(s) in [their] area who specialize in [Stryker’s] minimally invasive treatments”).

requests are regularly being rejected, and that in turn telehealth platform physicians will understand their employment is dependent on their continuing to write the requested prescriptions. Such a purely symbiotic relationship, without more, will pose a substantial challenge to an enforcer seeking to prove a violation of the Anti-Kickback Statute, while at the same time accelerating the degradation of the physician-patient relationship. Under such arrangements, patients are essentially encouraged to view physicians as nothing more than a necessary sign-off for the patient's pre-determined prescription request, with patients steered to the physicians most willing to provide that sign-off with minimal questions asked.

B. Legal Tools to Protect the Physician-Patient Relationship

While structures involving patients, doctors, telehealth platforms, and pharmaceutical manufacturers continue to evolve, it can be anticipated the parties will identify ways to operate under existing law while funneling patients to physicians highly motivated to write particular prescriptions. The focus of the 2025 Senate Report reflects the inadequacy of current law to address the issue. The 2025 Senate Report focused on “telehealth platforms launched by pharmaceutical manufacturers . . . with telehealth companies they have paid,” and focused on the Anti-Kickback Statute as the potential solution.¹⁰⁰ But the problem in DTP arrangements stems not only from the potential relationship between manufacturers and telehealth platforms, but from the relationship between physicians and their patients. The Anti-Kickback Statute is a poor tool to address degradation of the physician-patient relationship or substandard medical practice, and as described above, is a limited weapon for enforcers seeking to limit the degradation resulting from DTP arrangements. On the other hand, the role of overseeing the practice of medicine and professional relationships has traditionally been held by states via medical board licensure authority and tort law.

Scholars and legislators have considered situations where relationships between manufacturers and physicians may be legitimate from a safe harbor perspective, but still significant because of the potential that the payments will influence the doctor's decision-making. Scholars have focused on the fiduciary duty owed by doctors to their patients and expressed concern patients may be acting on advice from their doctors unaware their doctor may be influenced by a financial relationship with a manufacturer. Nadia Sawicki has persuasively argued the ethical foundations of informed consent together

¹⁰⁰ DURBIN ET AL., *supra* note 10, at 1, 13.

with “contemporary understandings of patient decision-making” processes support broad disclosure requirements, though such arguments have yet to carry the day with courts or legislatures.¹⁰¹ In an argument largely overlapping with that of the Supreme Court of California in *Moore v. Regents of University of California*,¹⁰² Sawicki concludes that “an ideal model would require physicians to disclose any information they are uniquely qualified to provide that would be material to a reasonable patient’s decision about what kind of medical treatment to pursue.”¹⁰³

Here, the concern is different. Patients reaching out to an entity advertising access to a prescription are likely unconcerned with whether the physician writing the prescription has a financial tie to the manufacturer of the medication they are seeking—the patient may assume it, or more likely gives little thought to the motivations of one part of the transaction the patient is seeking. Instead, the concern is structural—the Food and Drug Administration has approved the medications not for over-the-counter (OTC) sales, but only for distribution to patients with valid prescriptions.

The FDA’s analysis aside, the DTP Model represents a stark departure from the traditional view of the doctor-patient relationship. But unlike the problems envisioned by legislators and scholars who have looked to the Anti-Kickback Statute, the Stark Law, the Sunshine Act, and other statutes to protect patients from doctors influenced by manufacturers, here there is a need to protect the system from a version of the practice of medicine. Even prohibitions on the corporate practice of medicine—enacted in response to concerns about the commercialization of the medical profession and fear patient care would be subservient to profit motive—did not envision a scenario where the patient could be complicit in such a nakedly transactional version of the physician-patient relationship.¹⁰⁴ Here, of course,

¹⁰¹ Nadia N. Sawicki, *Modernizing Informed Consent: Expanding the Boundaries of Materiality*, 2016 U. ILL. L. REV. 821, 825 (2016). [<https://doi.org/10.2139/ssrn.2610766>].

¹⁰² *Moore v. Regents of Univ. of Cal.*, 793 P.2d 479, 485 (Cal. 1990). Courts since *Moore*, however, have generally not recognized an obligation for physicians to disclose financial interests. See Kate Greenwood, *Physician Conflicts of Interest in Court: Beyond the “Independent Physician” Litigation Heuristic*, 30 GA. ST. U. L. REV. 778 (2014). But see *D.A.B. v. Brown*, 570 N.W.2d 168, 171 (Minn. Ct. App. 1997) (finding that failure to disclose kickback scheme is an informed consent issue).

¹⁰³ Sawicki, *supra* note 101, at 869 (including “conflicts of interest” among the list of information that may fall within the physician’s “unique knowledge and expertise,” but noting that the information potentially subject to disclosure under Sawicki’s model “may need to be limited for pragmatic and policy reasons”).

¹⁰⁴ See Erin C. Fuse Brown & Mark A. Hall, *Private Equity and the Corporatization*

the patient is well aware of the nature of the doctor-patient relationship leading to their prescription, as they have specifically sought it out. From that perspective, it is remarkable the DTP Model has seen so little pushback from regulators. Analogizing again to opioids, it is difficult to imagine allowing patients to visit a doctor's office under the condition they will only be required to pay for the evaluation if the doctor writes them a prescription for an opioid. Yet that is precisely what patients agree to when they sign-up for an online evaluation through various DTP websites—they need only pay if their prescription request is approved.¹⁰⁵

Just as health care enforcers were slow to intervene in cases of physicians improperly prescribing opioids to drug-seeking patients, the DTP Model has thus far largely avoided scrutiny by declining to accept insurance, including government program insurance, and focusing on self-pay by patients. Enforcement scrutiny has historically been tied to financial losses, particularly to government health care programs.¹⁰⁶ Just as with most improper opioid prescribing, there is no financial loss to a health care program when a patient is permitted to pay for a prescription drug they want, even if writing of the prescription was improper, and the drug-seeking patient will certainly not complain.

But the patient seeking a prescription through a DTP Model is unconcerned with what health care law must consider—the impact of the model on the doctor-patient relationship. Having gone to the website in order to obtain a particular prescription, the patient is likely unbothered if the doctor has a conflict of interest, so long as the conflict is leading the patient to get the product they want. Health care law, however, must consider the sanctity of the relationship. Noting that the doctor-patient relationship represents a “deeply personal type of trust . . . paralleled only in fraternal, family, or love relationships,” Mark Hall has argued “[p]reserving, justifying, and enhancing trust is a prominent objective in health care law and public policy.”¹⁰⁷

Sam Halabi has noted that “physicians are among the most admired

of Health Care, 76 STAN. L. REV. 527, 563 (2024).

¹⁰⁵ The telehealth company, presumably, has agreed to pay the physician for the evaluation even if a prescription is not written, using online screening questions before involving the physician to reduce the likelihood of an evaluation leading to a physician-rejected request.

¹⁰⁶ See Jacob T. Elberg, *Money Over Everything*, MO. L. REV. (forthcoming).

¹⁰⁷ See Mark A. Hall, *Law, Medicine, and Trust*, 55 STAN. L. REV. 463, 470–71 (2002), [<https://doi.org/10.2307/1229596>].

and respected professions . . . precisely [because of their fiduciary relationship with patients.]”¹⁰⁸ Max Mehlman has persuasively argued that changes in the health care system threaten to “transform medicine from a calling into a mere business enterprise,” and that as physician power erodes and economic incentives challenge medical professionalism, “[i]f physicians want to regain and sustain their status as professionals, it is imperative for them to reaffirm their status as fiduciaries for their patients.”¹⁰⁹ The harm from the DTP Model may not stem from the prescriptions written pursuant to the model, but instead from the model’s impact on doctor-patient relationships more broadly. Viewed in that way, the transactions are not victimless and there is a need for government intervention.

III. POLICY PROPOSALS - CLOSING THE EXISTING LEGAL GAPS IN OVERSEEING THE DTP MODEL

A. State Licensing Boards Should Address Medical Standards of Care, thus Empowering Department of Justice Enforcement through the False Claims Act

A key concern posed by DTP Model, and especially those arrangements directly involving pharmaceutical manufacturers, is the erosion of the physician-patient relationship. There is thus a need to address the growth of this model, and the Anti-Kickback Statute is inadequate to protect against this risk do so. State medical boards’ licensing authority could offer better protection against substandard clinical evaluations and financially motivated prescriptions encouraged by tele-pharma partnerships and may serve as a hook for broader federal enforcement under the False Claims Act.

Though observers have rightly questioned the effectiveness of licensing boards due to limited resources and other concerns, licensing boards’ institutional competence makes them particularly well-suited for this

¹⁰⁸ Sam F. Halabi, *Against Fiduciary Utopianism: The Regulation of Physician Conflicts of Interest and Standards of Care*, 11 U.C. IRVINE L. REV. 433, 437 (2020) (referring to the physician-patient relationship as “one of the storied fiduciary relationships in law”).

¹⁰⁹ Maxwell J. Mehlman, *Why Physicians Are Fiduciaries for Their Patients*, 12 IND. HEALTH L. REV. 1, 62–63 (2015). [<https://doi.org/10.18060/18959>] (arguing persuasively that a fiduciary relationship does exist).

responsibility.¹¹⁰ Licensing boards have the necessary expertise to make judgments surrounding what constitutes a physician-patient relationship sufficient for prescribing, as well as to consider whether it is appropriate to make distinctions based on the specific items being prescribed. Licensing boards may decide, for example, to require in-person examinations before certain pharmaceuticals are prescribed, while not requiring them for others, in addition to maintaining a minimum level of relationship before the physician can write any prescription. More importantly, and more easily done, licensing boards should address the appropriateness of relationships between physicians and DTP entities, forbidding physicians from accepting money from entities that have a financial stake in the physicians' writing of particular prescriptions.

Broader concerns about the effectiveness of licensing boards as enforcers are particularly acute here, as licensing board authority extends only to practitioners, not to pharmaceutical manufacturers or telehealth companies. Licensing boards would thus have only the ability to seek discipline of physicians who violate its regulations, but not to bring actions against the primary actors—the pharmaceutical manufacturers and telehealth companies creating the direct-to-consumer prescription models and recruiting physicians to take part. Moreover, medical boards have largely been under-resourced and ill-equipped to enforce broad industrial changes and changing professional norms rather than individual disciplinary charges.

A further challenge of relying on state licensing authority to police DTP telehealth providers is that a few states allow telehealth services to be provided to in-state patients without an in-state license, but through a more limited registration or certification process.¹¹¹ Many more states participate through an interstate licensing compact that streamlines the process for providers to obtain licenses in multiple states.¹¹² In these states, imposing a state licensing requirement might be avoided by DTP platforms unless the telehealth registration or compact process explicitly extended the requirements to these out-of-state providers.

Although it is unrealistic at this moment in time to expect state licensing boards to lead enforcement efforts in this area, licensing boards

¹¹⁰ See MARC. A RODWIN, *MEDICINE, MONEY & MORALS: PHYSICIANS' CONFLICTS OF INTEREST* 115–17 (1993).

¹¹¹ <https://telehealth.hhs.gov/licensure/licensing-across-state-lines#telehealth-registration>

¹¹² <https://www.venable.com/insights/publications/2022/12/developments-in-interstate-telehealth-licensing>

creation of rules would be sufficient to empower the Department of Justice and whistleblowers to pursue enforcement through the False Claims Act.

The FCA is “the weapon of choice in the federal government’s battle against health care fraud.”^{113,114} In Fiscal Year 2023, for example, DOJ recovered \$1.8 billion from settlements and judgments in False Claims Act cases involving the health care industry.¹¹⁵ Between 2010–2023, DOJ recovered \$35.9 billion from settlements and judgments in False Claims Act cases involving the health care industry.¹¹⁶ False Claims Act recoveries have for decades been DOJ’s primary method of targeting organizations for health care enforcement, and that trend is expected to continue. DOJ has reported opening more than 400 new False Claims Act cases involving health care fraud each year between 2010 and 2023.¹¹⁷ The False Claims Act imposes penalties on anyone who “knowingly presents . . . a false or fraudulent claim for payment or approval” to the federal government, with violations of the Anti-Kickback Statute or of other laws or regulations potentially leading to

¹¹³ Jeffrey B. Hammond, *What Exactly is Healthcare Fraud After the Affordable Care Act?*, 42 STETSON L. REV. 35, 50 (2012); see also Lewis Morris & Gary W. Thompson, *Reflections on the Government’s Stick and Carrot Approach to Fighting Health Care Fraud*, 51 ALA. L. REV. 319, 327 (1999) (referring to the False Claims Act as “the government’s primary weapon against fraud” and pointing to the FCA’s *qui tam* provision as a primary reason for its growth); Pamela H. Bucy, *Growing Pains: Using the False Claims Act to Combat Health Care Fraud*, 51 ALA. L. REV. 57, 59–60 (1999) (concluding that the FCA’s *qui tam* provision, lower mens rea requirement, and lower burden of proof, combined with the fact that most health care providers have substantial assets, makes the FCA a “potent and appropriate weapon to use against fraudulent health care providers”); Timothy Stoltzfus Jost & Sharon L. Davies, *The Empire Strikes Back: A Critique of the Backlash Against Fraud and Abuse Enforcement*, 51 ALA. L. REV. 239, 247 (1999) (noting DOJ’s increasing reliance on the FCA to prosecute health care offenses).

¹¹⁴ U.S. Department of Health and Human Services (“HHS”) Office of Inspector General (“OIG”) maintains a separate authority to bring civil monetary penalty (“CMP”) actions based on a wide range of program violations. However, the size of CMP actions and resulting publicity from those actions has paled in comparison to FCA recoveries.

¹¹⁵ *False Claims Act Settlements and Judgments Exceed \$2.68 Billion in Fiscal Year 2023*, U.S. DEP’T OF JUST., OFF. OF PUB. AFFS. (Feb. 22, 2024) <https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-268-billion-fiscal-year-2023> [<https://perma.cc/7TPY-CAXQ>].

¹¹⁶ *Id.*; *Fraud Statistics - Health and Human Services*, CIVIL DIVISION, U.S. DEP’T OF JUST. (2023), <https://www.justice.gov/opa/media/1339306/dl?inline>.

¹¹⁷ *Fraud Statistics - Health and Human Services*, CIVIL DIVISION, U.S. DEP’T OF JUST. (2023), <https://www.justice.gov/opa/media/1339306/dl?inline>.

liability under the False Claims Act.¹¹⁸

In *Universal Health Services v. United States ex rel. Escobar*, the Supreme Court upheld the validity of the “implied false certification” theory of False Claims Act liability, meaning a defendant may be liable under the False Claims Act for submitting a claim that falsely implies compliance with material statutory and regulatory requirements.¹¹⁹ In *Escobar*, the defendant mental health service provider was alleged to have engaged in serious violations of regulations pertaining to staff qualifications and licensing requirements. Patients were treated—counseled and prescribed drugs—by unlicensed and largely unsupervised employees.¹²⁰ The Supreme Court held the defendants could be liable under the False Claims Act as long as the government would not have paid for the services if it had been aware of the regulatory violations.¹²¹ Because the government will only pay for prescription pharmaceuticals where a valid prescription has been written, the Department of Justice would likely succeed in arguing it would not pay for prescriptions written by physicians who wrote them in violation of state licensing board regulations.¹²² Importantly, False Claims Act liability would not be limited to the prescribing physicians, but would extend to pharmaceutical manufacturers and telehealth companies. Thus, even without licensing boards taking on enforcement responsibility, their creation of regulations would provide better resourced prosecutors with the tool necessary to pursue enforcement actions against the more culpable and more deterrable actors in the system.

The deterrent value of a licensing-board driven False Claims Act theory would be significant, but not complete. Because the False Claims Act

¹¹⁸ 31 U.S.C. § 3729(a)(1)(A) (2018).

¹¹⁹ *Universal Health Servs. v. United States ex rel. Escobar* 579 U.S. 176, 181 (2016).

¹²⁰ *Id.* at 183. The patient at the center of the case had been diagnosed by a practitioner who “identified herself as a psychologist with a Ph. D., but failed to mention that her degree came from an unaccredited Internet college and that Massachusetts had rejected her application to be licensed as a psychologist.” *Id.*

¹²¹ *Id.*

¹²² The claims in *Escobar* itself were based on violations of state licensing requirements. *Id.* at 184–85; see also Settlement Agreement at 3, *United States et al. ex rel. T.J. Novak v. Walgreens Boots Alliance, Inc.*, No. 18 C 5452 (N.D. Ill. Apr. 18, 2025), <https://www.justice.gov/opa/media/1397186/dl?inline> (listing among bases for \$350 million False Claims Act settlement that Walgreens filled prescriptions “not issued in the usual course of professional practice”).

only applies to claims to the federal government, the False Claims Act would not be useful to prevent most DTP arrangements currently in place. It would, however, prevent the continued expansion of such programs into government health care programs. With that limitation in place, licensing boards' more limited deterrent value as directed against physicians may be sufficient to dissuade physicians from taking part. Perhaps most importantly, licensing board regulations would have significant symbolic value in defending the doctor-patient relationship, making clear what interactions are consistent with appropriate physician practice.

As the use of telemedicine has grown over the past two decades, scholars have urged state regulators to work towards common minimum standards and limitations for the appropriate "practice of medicine."¹²³ They have identified some aspects of a reasonable floor for a doctor-patient relationship, including a focus on continuity of care through examination of the patient's medical existing records, minimum requirements for the doctor-patient interaction leading to the prescription, and a commitment to follow-up post-prescribing.¹²⁴ While some have encouraged an in-person requirement for at least an initial visit, others have questioned whether an in-person requirement is necessary or truly beneficial given the tradeoffs such requirements impose in terms of decreasing access to care.¹²⁵

A focus on the physician-patient relationship that does not take into account the relationship between the physician and their employer ignores an obvious and powerful conflict of interest. A 2015 RAND study found antibiotics were prescribed at about the same rate by office-based physicians and telemedicine physicians.¹²⁶ Other studies have suggested telemedicine physicians have prescribed antibiotics at a higher rate than office-based physicians.¹²⁷ But none of these studies have examined the modern DTP

¹²³ See Nicolas P. Terry, *Prescriptions sans Frontières (or How I Stopped Worrying About Viagra on the Web but Grew Concerned About the Future of Healthcare Delivery)*, 4 YALE J. HEALTH POL'Y L. & ETHICS 183, 263 (2004).

¹²⁴ *Id.* at 264; Laura C. Hoffman, *Shedding Light on Telemedicine & Online Prescribing: The Need to Balance Access to Health Care and Quality of Care*, 46 AM. J.L. & MED. 237, 242 (2020), [<https://doi.org/10.1177/0098858820933497>].

¹²⁵ See Hoffman, *supra* note 124, at 248.

¹²⁶ Lori Uscher-Pines et al., *Antibiotic Prescribing for Acute Respiratory Infections in Direct-to-Consumer Telemedicine Visits*, 175 JAMA INTERN. MED. 1234, 1235 (2015), [<https://doi.org/10.1001/jamainternmed.2015.2024>].

¹²⁷ Kristin N. Ray et al., *Antibiotic Prescribing During Pediatric Direct-to-Consumer Telemedicine Visits*, 143 PEDIATRICS 1 (2019),

Model, in which the telemedicine entity paying the physician is only paid if a prescription is written. Though there is no available data about the percentage of prescription requests rejected by the “examining” doctors working for entities such as Hims & Hers, it is impossible to imagine the doctors are rejecting a meaningful percentage of patients who have made it through the websites’ online screening tools—the doctors are evaluating the appropriateness of a prescription their employer has already determined is appropriate. Whether unconflicted doctors are more likely to write a prescription when examining a patient online versus in-person is an interesting question worthy of further study. No such study is needed to know doctors paid by entities that only make money when prescriptions are written have a conflict too big to ignore.

State licensing boards should not only further articulate minimum standards for physician-patient relationships but should also address what relationships between physicians and telemedicine entities are not appropriate.¹²⁸ Also in response to the opioid epidemic, New Jersey enacted rules governing the relationship between pharmaceutical manufacturers and physicians, prohibiting physicians from accepting more than \$10,000 annually from pharmaceutical manufacturers, even if the payments are for services that would fall under the Anti-Kickback Statute’s safe harbors.¹²⁹

In the case of DTP arrangements, such a bright line prohibition on financial relationship between prescribers and the DTP entities who profit from the prescription, is likely more important. Those envisioning lengthy, in-depth examinations with physicians who have sought, obtained, and reviewed all prior medical records are imagining an ideal which now rarely exists. Financial pressures have shortened the length of even in-person examinations, and a significant number of patients lack a meaningful relationship with a primary care provider.¹³⁰ Primary care doctors seeing a new patient are likely to accept, but not demand, medical records covering the patient’s prior treatment from other providers. Short visits with examining doctors who have not reviewed the patient’s prior medical records are not

[<https://doi.org/10.1542/peds.2018-2491>].

¹²⁸ *Prescribing for Pain: Opioid Abuse Prevention*, N.J. DIV. OF CONSUMER AFFS., (Sep. 8, 2020), <https://www.njconsumeraffairs.gov/prescribing-for-pain> [<https://perma.cc/EEQ7-CM3K>].

¹²⁹ N.J. ADMIN. CODE § 13:45J (2024).

¹³⁰ David Mechanic, Donna D. McAlpine & Marsha Rosenthal, *Are Patients’ Office Visits with Physicians Getting Shorter?*, 344 NEJM 198, 198 (2001), [<https://doi.org/10.1056/NEJM200101183440307>].

unique to telemedicine in today's health care system. The meaningful difference between a typical in-person physician visit and a "visit" with a DTP physician may not be its length or even the questions asked, but that the in-person doctor is expected to be conflict-free while the telemedicine doctor is presumed captured by the entity employing them and the prescription-on-demand DTP model.¹³¹

Focusing on the relationships between physicians and telemedicine companies brings with it an additional benefit, as it avoids the truly challenging work of determining what should be required as part of the physician-patient relationship. Where applied to a physician with no financial motive, explicit or implicit, to write a prescription, it is not easy to determine where the minimum level of care line should be drawn, recognizing that additional requirements have the potential to limit access to care. The answers may be different from state to state, depending on analyses of access to care, and even more likely may be different depending on the drug being prescribed. In order to cover a broad range of situations (such as the prescribing of drugs with varying benefits, risks, and costs), it may be challenging for licensing boards to come up with clear and definite rules. The detailed and specific prescribing rules enacted by New Jersey were specific to opioids, and would be seen as unnecessarily onerous in the context of less risky drugs.¹³² Current state licensing board regulations are generally vaguer—open to differences of opinion and judgment in a way that may be helpful to encouraging proper care while preserving access, but makes enforcement challenging. Rules declaring it improper for a physician to accept money for conducting a patient examination from an entity that will benefit financially from a prescription written based on that examination would draw a bright line both easy to follow and to enforce if violated.

Thus, to address the conflicts of interest in DTP arrangements, we propose that state medical boards adopt bright line rules prohibiting physicians from receiving any compensation directly or indirectly for evaluating patients from a telehealth company or other entity, including pharmaceutical companies or affiliated pharmacies, that financially benefit

¹³¹ See Terry, *supra* note 123, at 256 ("the bricks-and-mortar physician is less likely to have a financial interest in the dispensing part of the business than her online counterpart" because of the Anti-Kickback Statute and the Stark Law). As detailed above, telemedicine entities have now figured out how to structure relationships with doctors so they are also within the confines of the Anti-Kickback Statute and the Stark Law, as they do not technically have the "financial interest in the dispensing part" Terry feared. But Terry's larger point, and the conflicts, remain even under these currently lawful arrangements.

¹³² *Prescribing for Pain: Opioid Abuse Prevention*, *supra* note 128.

from the physician's prescription for outpatient prescription drugs.

Such rules would not apply only to tele-prescribing arrangements, as the concern is not the nature of the interaction between the physician and the patient (telehealth vs. in-person), but instead the conflict created by the doctor's relationship with an entity benefitting only when the doctor elects to write a prescription. These concerns are exacerbated by the ability of telehealth to connect patients with conflicted doctors on a massive scale, but remain even in an office setting.

Because the problem is having an entity with an economic interest in a prescription being written paying a physician to evaluate patients, such rules would not need to distinguish between situations where the entity is paying the doctor per prescription or per evaluation, or whether the entity is paying the doctor a salary, per hour, or per patient evaluation—no matter the arrangement, the conflict is unavoidable if the financial prospects of the doctor's employer hinge on whether or not the doctor chooses to write a prescription.

Nor does the type of entity matter. While DTP arrangements have to-date focused on fully integrated relationships with money made through furnishing of the drugs themselves, the same concerns would arise if the entity provided a prescription and stopped short of furnishing the drugs directly. A pharmaceutical company paying a doctor to do patient evaluations where the company will benefit if the doctor prescribes the company's drugs, for example, would raise similar concerns. As would a telehealth entity through which consumers only pay for an evaluation if a prescription is written.¹³³

As with licensing board regulations focused on the requirements of a patient examination, violations of the proposed regulations—banning direct or indirect compensation of physicians to evaluate patients by drug-providing telehealth companies, pharmaceutical companies, and affiliated pharmacies that benefit financially from the physician's prescription—would give rise to False Claims Act liability for any prescriptions paid for by government health care programs. A clear prohibition on direct and indirect financial relationships would address the conflict of interest created by the DTP Model. False Claims Act liability would deter prescribers as well as the

¹³³ Both Ro and Hims & Hers only charge patients if a prescription is written—there is no charge if the physician determines a prescription would not be appropriate. Thus, the entity financially benefits from the physician's decision to write a prescription. That would be true whether the patient obtained the drugs themselves or solely a prescription at the end of a successful transaction.

telehealth and pharmaceutical companies upstream from participating in these arrangements. Further, setting forth a standard would communicate that such relationships are inconsistent with the longstanding public policy and professional ethical command that physicians be free of conflicts in their clinical decisions.

Regulation focused on banning financial relationships between physicians and drug-providing telemedicine companies would be consistent with the rationale behind both corporate practice of medicine (CPOM) regulations and fee-splitting laws. Both arose out of concerns about physicians with divided loyalties, and share the thematic concern present here of physicians improperly influenced by nonprofessionals.¹³⁴ Recent scholarship has proposed that under the implied false certification theory, violations of state prohibitions on CPOM could form the basis of federal FCA liability.¹³⁵ But both corporate practice of medicine regulations and fee-splitting laws have suffered from eroded enforcement and clever contractual workarounds.

Most DTP telehealth companies structure their operations through the management services organization–professional corporation (MSO–PC) model to comply with state CPOM restrictions. Under this model, the MSO, an unlicensed non-clinical entity, manages business functions such as marketing, technology, billing, and pharmacy integration, while the PC, owned by licensed physicians, technically employs the clinicians who evaluate patients and make clinical prescribing decisions.¹³⁶ DTP telehealth platforms typically engage physicians on an exclusive basis via the telehealth platform’s MSO. Through management service agreements, operational control and revenues flow back to the MSO, allowing the telehealth company to effectively control the enterprise while maintaining the legal fiction of physician autonomy.¹³⁷ The loss of professional autonomy through MSO

¹³⁴ See Fuse Brown & Hall, *supra* note 104, at 562–73.

¹³⁵ Xusong Du, Note, *Enforcing the Corporate Practice of Medicine Doctrine Through False Claim Liability*, 125 COLUM. L. REV. 837, 842 (2025).

¹³⁶ See Hayden Rooke-Ley et al., *The Corporate Backdoor to Medicine: How MSOs Are Reshaping Physician Practices*, MILBANK MEM’L FUND (Apr. 28, 2025), <https://www.milbank.org/publications/the-corporate-backdoor-to-medicine-how-msos-are-reshaping-physician-practices/>.

¹³⁷ See, e.g., *Eli Lilly & Co. v. Aios Inc.*, No. 4:25-cv-03535 (N.D. Cal. filed Apr. 23, 2025); *Eli Lilly & Co. v. Mochi Health Corp.*, No. 3:25-cv-03534 (N.D. Cal. filed Apr. 23, 2025) (alleging that telehealth platforms Fella Health and Mochi Health violated California’s prohibition on the corporate practice of medicine by unlawfully controlling medical decisions to be made by contracted physicians’ prescribing decisions and clinical

controls further degrades the physician-patient relationship. As noted above, while the MSO-PC structure is common to other forms of corporate physician control, the DTP model poses an extreme version of corporatization with tight constraints on professional autonomy and clinical discretion for a narrow range of clinical indications. States could limit clinical control exercised by non-clinicians and safeguard physician independence through stronger corporate practice of medicine laws.¹³⁸ Stronger CPOM laws could prevent the telehealth platform's MSO from exerting control over clinical decisions by making it unlawful for any unlicensed owner, manager, or contractor to direct, control, or materially influence the professional judgment of any licensed physician, including through compensation structures, protocols, or operational policies. States have been exploring ways to strengthen their CPOM laws to limit control by corporate MSOs over contracted physicians in a variety of contexts.¹³⁹ These updated laws can be used to limit corporate telehealth platforms' use of MSOs to control physicians' prescribing decisions. Such is the extent of DTP platforms' control over their physicians that CPOM laws that tightly restrict the MSO-PC model pose an existential threat to the DTP telehealth industry. It is telling that recent state legislation in Oregon, widely considered the most restrictive CPOM law enacted to date, contains a heavily lobbied exception for telehealth providers.¹⁴⁰ If the provisions of these stronger CPOM laws were applied to telehealth, the DTP model would fracture as the telehealth platform lost the ability to control the

formulations, dosage, titration of compounded GLP-1s prescribed to their customers).

¹³⁸ These are state laws based on the prohibition on the unlicensed practice of medicine that generally prohibit unlicensed lay-entities from owning or controlling physicians or interfering with clinical decision-making. Jane M. Zhu, Hayden Rooke-Ley & Erin Fuse Brown, *A Doctrine in Name Only — Strengthening Prohibitions against the Corporate Practice of Medicine*, 389 NEJM 965 (2023), [<https://doi.org/10.1056/NEJMp2306904>].

¹³⁹ See e.g., S.B. 951, 83d Leg. Assemb., Reg. Sess. (Or. 2025) (strengthening Oregon's CPOM law to address the MSO-PC relationship, but exempting telehealth companies from the law's applicability); S.B. 351, 2025–2026 Reg. Sess., ch. 409, 2025 Cal. Stat. (codifying California's prohibition on private-equity backed MSOs from interfering with the professional judgment of or exercising control over physicians); see also Erin C. Fuse Brown, *State Efforts to Rein in Corporate Medicine*, LPE PROJECT (July 2, 2025), <https://lpeproject.org/blog/state-efforts-to-rein-in-corporate-medicine/>.

¹⁴⁰ Jane M. Zhu & Hayden Rooke-Ley, *Regulating Corporate Control in Health Care — Oregon's Attempt to Revive the CPOM Doctrine*, 393 N ENGL J MED 1972 (2025), <http://www.nejm.org/doi/10.1056/NEJMp2508442>.

captive physicians and clinicians whose prescriptions are necessary for the model to profit.¹⁴¹ In short, with a stronger CPOM prohibition, offering DTP telehealth services as they are currently constituted would become unlawful in the state.

Thus there are two powerful actions states could take to address the conflicts of interest inherent in the DTP Model. First would be for medical licensing boards to impose regulations preventing physicians from receiving compensation from entities that will make money from the physicians' prescribing. Second, states could strengthen their corporate practice of medicine doctrine to prohibit unlicensed corporations from exerting *de facto* control over physicians—and apply these prohibitions to telehealth providers serving patients in the state. Violations of both prohibitions could be enforced via the federal False Claims Act if federal program dollars are involved. Given the nature of the conflict at issue, and the limited reach of some states' licensing laws over out-of-state telehealth providers, the inherently conflicted DTP relationships should also be forbidden by federal statute.

B. A New Federal Statute Should Squarely Address the Direct-to-Prescription Model

Just as the Anti-Kickback Statute and Stark Law prohibit certain relationships regardless of whether they would violate state licensing rules, the rise of direct-to-consumer prescribing calls for a new statute to protect both the physician-patient relationship and health care programs. While licensing boards can play an important role both in articulating norms surrounding the doctor-patient relationship and guidance as to what specific actions are appropriate, DTP arrangements raise fundamental issues striking at the heart of the doctor-patient relationship and more easily solved through federal legislation. By enacting a statute requiring separation between physicians—who are expected to provide unbiased advice to their patients—and entities benefitting from the physicians' decisions to write a prescription, the numerous benefits of telemedicine can be maintained while protecting the physician-patient relationship.

Legislators have recognized one category of issues arising from DTP

¹⁴¹ The telehealth lobbying group, ATA Action, has expressed significant concern that Vermont's 2026 bill to strengthen CPOM (H. 583) "would unnecessarily jeopardize this long-established model and disrupt access to care for the many Vermonters currently being served by telehealth entities." <https://www.americantelemed.org/wp-content/uploads/2026/01/VT-HB-583-ATA-Action-Letter.pdf>

arrangements, and have focused proposed legislation on advertising and promotion rules. In 2025, federal legislators proposed the Protecting Patients from Deceptive Drug Ads Act and the End Prescription Drug Ads Now Act.¹⁴² The former focused on social media advertisements by telehealth companies and sought to move those companies under the jurisdiction of the U.S. Food and Drug Administration. The latter sought to ban drug manufacturers from using direct-to-consumer advertising, including social media, to promote their products. Focusing on advertising from drug manufacturers and telehealth companies, neither proposal seeks to address the arguably more consequential impact of direct-to-consumer prescribing models—the relationship between patients and their doctors. Whether because of a mistaken belief that the Anti-Kickback Statute is sufficient or because drug manufacturers are a more politically palatable target than physicians, the legislative proposals do nothing to address the fundamental problem of prescription writing increasingly growing out of relationships far removed from the doctor-patient relationship the health care system envisions and relies upon.

As noted above, the Anti-Kickback Statute fails to address some DTP arrangements because of the Anti-Kickback Statute's safe harbors and its challenging *mens rea* requirement. Given the rapid rise in the DTP Model, and the potential it will grow even more rapidly as it gains mainstream acceptance, a new federal statute may be more effective and efficient than leaving the problem to state licensing boards. The new statute would address the structural problem created by arrangements where physicians are paid to conduct patient evaluations by entities having a financial interest in those evaluations leading to prescriptions.

If a physician has or will receive compensation, directly or indirectly, for conducting an examination or evaluation of a patient from an entity that has a financial interest in or benefits financially from the provision of an outpatient drug or medical product, the physician may not transmit or cause to be transmitted by means of wire, radio, or television communication in interstate or foreign commerce, a prescription or other authorization for the provision of such drug or medical product. Any person that violates or causes another to violate this statute shall be subject to a civil penalty or not more than \$15,000 for each prescription

¹⁴² Protecting Patients from Deceptive Drug Ads Act, S. 652, 119th Congress (Feb. 2025); End Prescription Drug Ads Now Act, S. 5040, 118th Congress (previously proposed in Sep. 2024).

or authorization.

None of the substantial benefits of telemedicine, detailed above in Part I.B., require use of a model through which a prescription-writing physician is paid to evaluate patients by an entity that will benefit if the physician elects to write a prescription for the patient. At the same time, the potential conflict of interest is powerful and unavoidable in the direct-to-patient prescribing model. Even if a physician is paid fair market value for their time evaluating a patient and is paid regardless of whether they write the requested prescription, the physician cannot escape the knowledge that the entity paying has a business model entirely dependent on the physician writing prescriptions. No amount of training or statements from the entity that the physician should only exercise their own medical judgment can compete with the physician's knowledge that their benefactor will only be paid if the prescription is written. Conversely, the independent physician who contracts with a telehealth platform that has no financial interest in the physician's prescriptions—that is, no pharmaceutical company partner or dispensing mail-order pharmacy and patients are charged for the evaluation even if a prescription is not written—will not run afoul of the statute. It is the financial incentive created by the vertical alignment of pharmaceutical company, telehealth platform or other MSO, affiliated dispensing pharmacy, and prescribing clinician that is the subject of this prohibition.

Like the Stark Law, the proposed statute would address relationships which, by their very nature, raise concerns about the impact of financial arrangements on physician decision-making. The Stark Law is commonly known as the “physician self-referral law” because it prevents physicians from making referrals to entities with which the physician has a financial relationship.¹⁴³ The goal of the statute is to discourage physicians from being influenced by financial considerations when making decisions regarding the proper treatment of their patients. Where a physician might make a referral to an entity with which they have a financial relationship, the potential conflict of interest is sufficiently concerning for the law to forbid it despite recognition that an individual referral may be appropriate and not driven by the conflict. The concern is so great that the Stark Law is a strict liability offense with no *mens rea* requirement. The rigidity of the Stark Law's strict

¹⁴³ 42 U.S.C. § 1395nn. The Stark Law only limits referrals for the furnishing of enumerated “designated health services.” Arrangements that would be implicated under the Stark Law, e.g., an arrangement involving compensation to a prescribing physician by a 340B hospital or by a practice that administers drugs in-office under Medicare Part B, which stand to profit from the physician's prescriptions, would be analyzed under the Stark Law if Medicare was billed for the service.

liability is tempered by it being a civil-only statute.

The Stark Law is far broader—addressing all financial relationships—thus necessitating numerous safe harbors to address financial relationships determined not to pose a risk of abuse for patients or the health care program. As importantly, without the safe harbors the Stark Law would forbid some financial relationships deemed beneficial to the health care system. But since the Stark Law only applies to financial relationships between certain entities, such as hospitals or clinics, and physicians, it does not apply to financial relationships between physicians and pharmaceutical companies. The proposed statute, on the other hand, would focus on only a particular type of arrangement—where physicians have direct or indirect financial relationships with entities benefiting financially from the writing of a prescription—and no safe harbors are necessary as the statute would not forbid any beneficial financial relationships and the risk of improper influence is too significant.¹⁴⁴

As with the proposed state medical board rules discussed above in Part III.A., the proposed statute would not apply only to tele-prescribing arrangements, would not distinguish based on the details of the financial relationship between the entity and the physician, and would not distinguish based on the type of entity. Because the problem is having an entity with an economic interest in a prescription being written paying a physician to evaluate patients, any such relationships will violate the statute.

Significantly, the proposed statute would broaden and strengthen government enforcement, providing an enforcement mechanism regardless of payor and a firm basis for cases under the False Claims Act where the prescriptions involve government health care billings. Unlike the Stark Law (and the Anti-Kickback Statute), the proposed statute would not be limited to government health care programs, or even to health care programs more broadly.¹⁴⁵ And where government health care programs are involved, the

¹⁴⁴ An open question remains whether there are some vertically-integrated models (eg. an HMO-owned pharmacy) policy-makers view as containing sufficient benefits to outweigh the concerns caused by the conflict of interest when a prescriber's employer benefits financially from a prescription. Safe harbors could potentially be added to address such instances, but we are skeptical that will be appropriate given the magnitude and impact of the conflict.

¹⁴⁵ The federal health care fraud statute, 18 U.S.C. § 1347, applies to fraud involving all health care programs, regardless of payor, but does not apply to health care fraud unconnected with a health care program (where a patient is paying for goods or services directly).

proposed statute would provide a basis for False Claims Act liability, just as the licensing-board driven False Claims Act theory described above.

As with the recommended licensing board actions detailed above, the proposed statute would not apply only to tele-prescribing arrangements, and would be applicable with equal force to situations in which the conflicted doctor performs the patient consultation in-person. As noted above, the concern is not telehealth itself, which offers significant system-wide advantages and possibilities for increasing access to care. The concern is allowing incentives which damage both the patient-physician relationship and physician's independent decision-making by having doctors paid to conduct evaluations by entities that are in the evaluation business specifically because they seek to maximize prescriptions. While the emergence of telehealth as the mechanism for prescription-on-demand arrangements has accelerated the need for a statute targeting the potential conflict, the conflict is no less problematic when the evaluation is conducted in-person.

The statute that would presumably be welcomed by the vast majority of physicians, for whom the move towards prescriptions-on-demand DTP arrangements interferes with their ability to maintain a physician-patient relationship in which physicians' expertise is valued and welcomed by patients.

While both proposals—one focused on state professional licensing authority and the other on a new federal statute—seek to address the substantial concerns arising out of DTP arrangements, they focus on different targets for enforcement and are intended to be mutually reinforcing. Thus, it may be beneficial to pair the state and federal policies rather than relying on one or the other. The former, by putting enforcement responsibility in the hands of state licensing boards, has the symbolic benefit of focusing on the professional obligations of physicians. And the benefits are more than symbolic, as for individual physicians there is likely more deterrent value in a threat of licensure suspension or loss than of a financial judgment. The proposal would empower licensing boards to take an active role in defining, and defending, expectations of a conflict-free physician-patient relationship. At the same time, this proposal is not sufficient on its own, as it would necessarily require action by licensing boards in each state, and potentially lead to a patchwork set of rules making federal enforcement against manufacturers (though possible through the False Claims) more challenging.

The latter, by focusing on a federal statute, provides simplicity of implementation and enforcement, and a mechanism for federal enforcement that would not require DOJ to base cases against pharmaceutical companies on dozens of potentially different state licensing rules. It would thus likely

provide a cleaner and more effective deterrent against pharmaceutical manufacturers, while lacking the likely deterrent impact on individual physicians, who are unlikely to be the target of federal enforcement. It would also eliminate the federal government's current reliance on the Anti-Kickback Statute, which is ill-equipped to address the substantial concerns raised by the rise of the DTP Model.

Implementing both recommendations will not eliminate the possibility of concerning relationships, including those connecting pharmaceutical manufacturers with physicians. But the proposals would fill what is now a substantial hole that is likely to increase rapidly if not checked.

IV. IMPLICATIONS: THE DIRECT-TO-PRESCRIPTION MODEL AND THE CORPORATIZATION OF MEDICINE

The issue of DTP arrangements exemplifies an emerging theme from the health law and policy literature: corporatization of medicine. The DTP Model exemplifies concerns that financial incentives to maximize profits for corporate investors overrides the professional ethical obligation of physicians to prioritize the patient's interest above all others.

Corporatization in health care has been characterized by the growing trend in the health care sector toward consolidated control by large, profit-seeking conglomerates.¹⁴⁶ Neoliberal economist Milton Friedman famously popularized the notion that the primary duty of a governing body and decisionmakers in a corporation is to maximize shareholder value.¹⁴⁷ When applied to the practice of medicine, a key policy concern of corporatization is that the physician's ethical and fiduciary obligations to prioritize the patient's welfare becomes subordinated to the corporation's duty to maximize profits for the corporate shareholder.¹⁴⁸

¹⁴⁶ Erin C. Fuse Brown, *Defining Health Care "Corporatization,"* 393 NEJM 1 (2025), [<https://doi.org/10.1056/NEJMp2415485>].

¹⁴⁷ Milton Friedman, *A Friedman Doctrine—The Social Responsibility of Business Is to Increase Its Profits*, N.Y. TIMES (Sep. 13, 1970), <https://www.nytimes.com/1970/09/13/archives/a-friedman-doctrine-the-social-responsibility-of-business-is-to.html>.

¹⁴⁸ Erin C. Fuse Brown & Hayden Rooke-Ley, *Health Care Financialization*, 29 J. HEALTH CARE L. & POL'Y 1, 12-14[<https://dx.doi.org/10.2139/ssrn.5384530>] (applying Friedman's shareholder primacy concept and the authors' definition of "financialization" to health care providers and describing the subordinating effect on physicians' fiduciary responsibilities to patients).

By contrast, the practice of medicine and the physician-patient relationship have been recognized as a fiduciary relationship, characterized as one of trust, vulnerability, and information asymmetry.¹⁴⁹ The potential for profit motive to corrupt the practice of medicine is a longstanding policy concern.¹⁵⁰ This tension between patients and profits has spawned a myriad of laws attempting to ameliorate financial conflicts of interest by physicians and regulate corporate control of the profession, including state laws restricting the corporate practice of medicine laws and fee-splitting laws as well as federal laws prohibiting kickbacks, illegal remuneration of providers, and self-referral arrangements in the Anti-Kickback Statute and Stark Law.¹⁵¹ Yet, as explained above, the Anti-Kickback Statute may be underpowered as an enforcement tool because these arrangements can be structured to avoid clear violations and due to the difficulty of proving they are structured with the intent to induce referrals. Moreover, the Anti-Kickback Statute is ill-equipped to address the erosion of trust in the professional-patient relationship or stretching of medical standards of care when physicians are paid to conduct cursory, online evaluations designed to generate prescriptions rather than to provide ongoing or holistic patient care.

The financial relationships created by DTP arrangements represent another manifestation of the corporatization of the medical profession.¹⁵² The physician-prescribers are mere cogs in a much larger transactional machinery powered by the pharmaceutical company, the telehealth platform, and the affiliated mail-order pharmacy. The DTP Model is designed to produce patient prescriptions and capture the revenues from across the supply-chain from manufacture to fulfillment. The primary financial benefits from

¹⁴⁹ Hall, *supra* note 107, at 489; Halabi, *supra* note 108 (referring to the physician-patient relationship as “one of the storied fiduciary relationships in law”); Mehlman, *supra* note 109.

¹⁵⁰ Ryan Crowley, Omar Atiq & David Hilden, *Financial Profit in Medicine: A Position Paper from the American College of Physicians*, 174 ANN. INTERN. MED. 1447 (2021), [<https://doi.org/10.7326/M21-1178>]; Marc A. Rodwin, *Conflicts of Interest, Institutional Corruption, and Pharma: An Agenda for Reform*, 40 J.L. MED. & ETHICS 511 (2012), [<https://doi.org/10.1111/j.1748-720X.2012.00683.x>] (discussing institutional corruption in medicine); Arnold S. Relman, *The New Medical-Industrial Complex*, 303 NEJM 963 (1980). [<https://doi.org/10.1056/NEJM198010233031703>].

¹⁵¹ Zack Buck, *Fraud, Abuse, and Financial Conflicts of Interest*, 388 NEJM 673 (2023), [<https://doi.org/10.1056/NEJMp2201628>].

¹⁵² Another contemporary example of corporatization is private equity’s investment into health care providers. See generally Fuse Brown & Hall, *supra* note 104, *passim*.

generated prescriptions go to the shareholders of the telehealth platform and affiliated pharmaceutical company—by generating more sales of the manufacturer’s product and capturing the revenue from dispensing the product through affiliated mail-order pharmacies. These partnerships also enrich the telehealth company by attracting investor capital and service revenue for assembling the online platform and contracting with a roster of prescribers to provide the requisite clinical evaluations to write the prescriptions. Neither the pharmaceutical company nor the telehealth company owe a fiduciary duty to the patient-customer; instead, they owe their primary duty to their shareholders.

The physician is the lone actor in the DTP machinery that owes a fiduciary and professional ethical duty to prioritize the patient’s interests. DTP arrangements reduce the fiduciary and trust-based physician-patient relationship to a mere transactional relationship. Physicians are a necessary input in the process, but the arrangement is designed to minimize the role of the telehealth prescriber’s independent clinical judgment or other traditional trappings of the physician-patient relationship. The physician-prescribers are fungible service workers whose job is to maximize patient volume and generate prescriptions. This fundamentally transactional role does not depend on whether the physician is paid per prescription, per visit, or per hour. Nor do the incentives vary based on who pays the physician: the telehealth company, pharmaceutical manufacturer, or a third-party payer. The corrupting influence stems from the fact that the entity or entities in control of the physician’s compensation stand to profit from the physician’s prescriptions.

This insight has policy design implications: the corporatizing effects of the DTP Model would be better addressed through clear restrictions on the financial arrangements themselves—without requiring proof of intent inherent in Anti-Kickback enforcement. Beyond a simple quid-pro-quo between two parties in a position to generate business for the other, the DTP Model demonstrates a trend toward complex, vertically integrated tech and retail platforms that link marketing, patient referral, clinical assessment, and prescription delivery. Our proposed medical board standards and federal statute focus on the problematic financial incentives that could lead to inappropriate prescribing and erosion of the physician patient relationship. We propose that direct or indirect compensation of the prescribing clinician for evaluating patients by any pharmaceutical company, telehealth platform, affiliated pharmacy, or other DTP entity should be prohibited where the entity has a financial interest in the prescriptions written. Further, because DTP arrangements represent an extreme version of corporatized medicine, the tools to constrain corporate influence and control over professional clinical

decisions are readily applicable here. In particular, stronger forms of the corporate practice of medicine doctrine currently emerging in states could be a powerful tool to reduce the financial conflicts inherent in the DTP model. Liability should not be avoidable by clever contracting, or complex compensation models or financial structures, because none of these would ameliorate the concern over the commercialization of the physician-patient relationship.

Beyond illuminating how policy should be structured, the framework of corporatization also illustrates why such policy might be needed. DTP arrangements exemplify degradation of the medical profession, where financial incentives can corrupt or commodify medical decision-making. The corporatization risk posed by the DTP Model extends beyond a concern for inappropriate prescriptions or overutilization—it is the erosion of trust in the medical profession that stems from such a transparently transactional relationship.

V. CONCLUSION

The DTP Model represents a profound shift in the organization of medical care—one that collapses the traditional separation between pharmaceutical marketing, clinical judgment, and drug dispensing into a single, revenue-maximizing pipeline. While telemedicine and consumer engagement have potential to improve access and convenience, this Article demonstrates that the DTP Model exploits those benefits to normalize a prescription-on-demand paradigm that is structurally incompatible with core commitments of medical professionalism. When physicians are compensated by entities whose business models depend on prescription volume, clinical judgment is inevitably subordinated to commercial imperatives, even in the absence of overt coercion or provable intent to induce.

Existing legal frameworks are ill-suited to address this structural problem. Fraud-and-abuse statutes such as the Anti-Kickback Statute are narrowly calibrated to protect federal payers and hinge on intent requirements that sophisticated actors can readily evade. State licensing oversight and corporate practice of medicine doctrines, meanwhile, have been weakened by under-enforcement and contractual evasion that preserve formal physician autonomy while eroding it in practice. As a result, DTP arrangements have proliferated largely unchecked, despite their capacity to fragment care, increase spending, and recalibrate patient expectations away from relational medicine toward transactional consumption.

This Article argues that addressing these risks requires refocusing on the physician-patient relationship as a protected professional institution. State

medical boards should articulate and enforce clear prohibitions on physicians' financial entanglement with entities that profit from their prescribing decisions, both to safeguard standards of care and to create enforceable predicates for federal False Claims Act liability. At the federal level, a targeted statute prohibiting prescription-writing under conflicted compensation arrangements would more directly confront the structural incentives driving DTP tele-prescribing, without sacrificing the genuine benefits of telemedicine.

Absent such intervention, the corporatization of prescribing threatens not only patient safety and public spending, but the integrity of medical judgment itself.