Prescriptions and Subscriptions: Examining Whether and How to Regulate Online Direct-to-Consumer Telemedicine "Platforms"

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I. INTRODUCTION

Modern healthcare goals are threefold: increase quality, decrease costs, and expand access.[1] But what should be done when those aims become mutually exclusive—when decreasing costs and expanding access reduce the quality of care? Telemedicine has vastly improved access to healthcare and contributed to lower healthcare costs in many contexts.[2] During the COVID-19 pandemic, certain companies took advantage of the surge in telemedicine to elevate their sales and status.[3] These companies, such as Hims and Hers, function as online

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[1] James Mold, *Goal-Directed Health Care: Redefining Health and Health Care in the Era of Value-Based Care*, 9 CUREUS e1043 (2017).

[2] SYDNE ENLUND & CAROLINE VESEY, NAT'L CONF. STATE LEGS., INCREASING ACCESS TO HEALTH CARE THROUGH TELEHEALTH, 1–3 (2019). People use telehealth and telemedicine interchangeably, though they have different scopes. Telehealth refers broadly to technological services used to provide healthcare remotely; telemedicine is narrower and refere to the practice of medicine via electronic mediums. *Id.* This Note refers only to telemedicine.

[3] Kristin V. Brown & Garrit De Vynck, *How Hims Built an Online Prescription Drug Empire on Outdated Oversight*, BLOOMBERG (Oct. 30, 2020),

direct-to-consumer (DTC) telemedicine platforms.[4] These platforms operate essentially as telemedicine intermediaries by connecting patients to third-party physicians who hold contracts with the platform.[5] Through direct-to-consumer advertising (DTCA), platforms entice consumers to utilize their services and obtain prescriptions for a variety of health conditions, ranging from anti-anxiety medications to birth control.[6] Patients choose a drug, complete an online health-assessment, connect with a doctor (with whom they never meet in-person), and usually obtain a prescription for the drug they seek.[7] Once a doctor prescribes a drug, the platform's subscription model activates, and the drug is delivered to the patient's door each month.[8]

Healthcare is a highly monitored industry, and the interplay between the federal and state governments creates a complex regulatory scheme.[9] Because platforms disclaim status as pharmaceutical companies or online pharmacies, they avoid federal regulations related to advertising and prescribing.[10] Similarly, because they disclaim status as healthcare providers, they escape some state telemedicine laws.[11] Because of the dichotomy between federal and state regulation, platforms operate in a regulatory gap, which impacts how they market to consumers.[12]

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https://www.bloomberg.com/news/features/2020-10-30/how-hims-built-an-online-prescription-drug-empire-on-outdated-oversight [https://perma.cc/H3F6-XPM9].

[4] Kristina L. Bitzer, *Online and Off-Label: Closing the Regulatory Gap in Online Direct-to-Consumer Drug Promotion and Prescribing*, 42 N. ILL. U.L. REV. 164, 167 (2021). Other examples include Kick Health, Ro, Zero, Rory, and Nurx. Yasmin Gagne & Burt Helm, *Buying Prescription Drugs Online Is Easier than Ever. But There Are Side Effects*, FASTCOMPANY (Sept. 11, 2019), https://www.fastcompany.com/90396205/buying-prescription-drugs-online-is-easier-than-ever-but-there-are-side-effects [https://perma.cc/VK8F-WKTE]. As used in this Note, the term "platform" refers to companies that do not manufacture drugs, but rather promote drugs for off-label uses and contract with third-party doctors who prescribe said drugs.

[5] Gagne & Helm, *supra* note 4.

[6] *Id.*; *see also* Natasha Singer & Katie Thomas, *Drug Sites Upend Doctor-Patient Relations: 'It's Restaurant-Menu Medicine'*, N.Y. TIMES (Apr. 2, 2019), https://www.nytimes.com/2019/04/02/technology/for-him-for-hers-get-roman.html [https://perma.cc/GD4B-HQW5].

[7] Gagne & Helm, *supra* note 4.

[8] *See, e.g.*, *Terms and Conditions*, HERS, https://www.forhers.com/terms-and-conditions [https://perma.cc/KR28-TPFK] (last updated Sept. 7, 2023).

[9] Robert I. Field, *Why Is Health Care Regulation So Complex?*, 33 PHARMACY & THERAPEUTICS 607, 607 (2008).

[10] *See generally* Bitzer, *supra* note 4.

[11] *Id.*

[12] Several scholars argue that platforms exploit a regulatory gap, effectively evading federal and state laws. *See, e.g.*, Bitzer, *supra* note 4, at 165; Kristen V. Brown & Gerrit De Vynck, *Startups Are Hawking Zoloft and Beta-Blockers for Off-Label Uses*, BLOOMBERG (Apr. 2, 2019), https://www.bloomberg.com/news/articles/2019-04-02/startups-are-hawking-zoloft-and-beta-blockers-for-off-label-uses [https://perma.cc/3XQ9-9DXS] ("The gap is between who can . . . regulate the practice of medicine, and who can regulate products and manufacturers.").

The advent of DTC telemedicine platforms has been met with both applause and criticism. On the one hand, supporters praise their role in increasing access to care and empowering individuals to seek treatment for conditions they otherwise might not.[13] Yet, others criticize the platform model for encouraging inappropriate prescribing and overprescribing, and the downstream negative consequences that has on health.[14] At the epicenter of the debate is disagreement about the role of the consumer in the healthcare context. The healthcare system in the United States has experienced a movement toward patient-centered care.[15] Patients are increasingly encouraged to play an active role in their healthcare experience, and DTCA is one mechanism to facilitate that involvement.[16] Meritorious qualities like informed consent and increased decision-making power are inherent in patient-centered care.[17] However, doctors, regulators, and consumers themselves have called into question the appropriateness of DTCA insofar as it encourages self-diagnosis and misleads consumers to pursue potentially inappropriate, unnecessary, or harmful treatment plans.[18]

Many scholars have discussed the benefits of the platform model as well as potential hazards associated with a lack of meaningful regulation in the online prescription space.[19] This Note focuses on the proper regulatory balance between federal and state governments. Part II briefly describes DTC telemedicine, the current regulatory landscape, and arguments both for and against greater platform regulation. Part III suggests a federalism-driven regulatory scheme, particularly modifications to state telemedicine laws. Part IV briefly concludes.

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[13] *See, e.g.*, Paige Minemyer, *Experts: COVID's Telehealth Boom Giving Patients an 'Overwhelming Drive for Self-Empowerment'*, FIERCE HEALTHCARE (Apr. 21, 2021), https://www.fiercehealthcare.com/tech/experts-covid-s-teleheath-boom-giving-patients-overwhelming-drive-for-self-empowerment [https://perma.cc/H7ST-WF5F].

[14] *See, e.g.*, Jessica Defino, *The Dangerous Side Effect of Digital Wellness*, FASHIONISTA (Mar. 20, 2019), https://fashionista.com/2019/03/digital-health-wellness-companies-government-regulations [https://perma.cc/CKB4-TFMW]; Brown & De Vynck, *supra* note 3 ("And yet Hims's real innovation isn't in destigmatizing embarrassing medical conditions. It's in making prescriptions extremely easy to get—maybe too easy . . . .").

[15] *See generally* Julie Donohue, *A History of Drug Advertising: The Evolving Roles of Consumers and Consumer Protection*, 84 MILBANK Q. 659, 662 (2006).

[16] *See id.* at 680–83.

[17] *Id.* at 660.

[18] *Id.* ("Underlying this policy debate are profound disagreements over the role of consumers in medical decision making, the appropriateness of consumers engaging in self-diagnosis, and the ethics of an industry promoting potentially dangerous drugs").

[19] *See generally, e.g.*, Bitzer, *supra* note 4.

II. LANDSCAPE IN WHICH DTC TELEMEDICINE PLATFORMS OPERATE

A. *Brief Introduction to DTC Telemedicine*

The application of telemedicine, use of DTCA, and off-labeling of drugs have all steadily increased in recent years; together they culminate in the platform model.[20] To start, platforms attract new patients by virtue of their flexibility. DTC telemedicine can occur where no physician-patient relationship exists.[21] So, patients can reach out to providers, no prior physician-patient relationship required, and yet still walk away with the prescription they wanted.[22] Users can log in from any location, answer questions about their medical history, select a treatment option, and quickly connect with a provider.[23] DTCA is, thus, a critical aspect of platform operations because it draws patients in.[24] Many of these platforms have grown because of their advertising efforts on social media and television.[25] In the context of prescription drugs, DTCA is a media-based effort—usually television, print, or Internet ads—by a pharmaceutical company that directly encourages patients to acquire the company's products.[26] And platforms maintain this practice through off-label promotion and prescribing.[27] Essentially, off-label prescribing occurs where one prescribes or administers an FDA-approved drug for a non-approved

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[20] *Id.* at 168–78. For a comprehensive history of the rise of telemedicine see generally THOMAS S. NESBITT & JANA KATZ-BELL, *Chapter 1: History of Telehealth*, *in* UNDERSTANDING TELEHEALTH (Karen Schulder Rheuban & Elizabeth A. Krupinski eds., 2022), https://accessmedicine.mhmedical.com/content.aspx?bookid=2217&sectionid=187794434 [https://perma.cc/7PT2-GFUZ].

[21] *See* Bitzer, *supra* note 4, at 168–69.

[22] Brown & De Vynck, *supra* note 3 (noting that "about 80% of patients seeking treatment for erectile dysfunction and hair-loss drugs were being approved").

[23] *See, e.g.*, *Welcome to Hers*, HERS, https://www.forhers.com/c/mh/welcome [https://perma.cc/DMC2-CTTF] (last visited Apr. 29, 2024).

[24] *See* 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, 240 (2020). For a comprehensive discussion of DTCA see, for example, Donohue, *supra*, note 15; Tania Elliot & Jennifer Shih, *Direct to Consumer Telemedicine*, 19 CURRENT ALLERGY AND ASTHMA REPS. 1 (2019); Barbara Mintzes et al., *How Does Direct-to-Consumer Advertising (DTCA) Affect Prescribing? A Survey in Primary Care Environments with and Without Legal DTCA*, 169 CMAJ 405, 405 (2003).

[25] *See, e.g.*, Hers (@hers), INSTAGRAM , https://www.instagram.com/hers/?hl=en [https://perma.cc/CR5J-Q8VY] (last visited Apr. 29, 2024); Hims, *Getting Help is Simple With Hims*, YouTube (July 19, 2023), https://www.youtube.com/watch?v=5HE3LC2XewA [https://perma.cc/LP8B-ZCJ8].

[26] C. Lee Ventola, *Direct-to-Consumer Pharmaceutical Advertising*, 36 PHARM. & THERAPEUTICS 669, 669 (2011).

[27] Hoffman, *supra* note 24, at 240.

purpose.[28] The current regulatory framework usually permits off-label prescribing by physicians because the FDA does not regulate the physician practice of medicine.[29] However, the FDA prohibits off-label promotion by pharmaceutical companies.[30] But, by virtue of the regulatory gap in which platforms operate, they can engage in off-label promotion by advertising certain drugs for non-FDA-approved uses.[31] In sum, telemedicine allows platforms to offer flexible services, DTCA facilitates their operations, and off-label promotion and prescribing account for much of their business.

B. *Current Regulatory Scheme*

Platform operations involve both drug advertising and drug prescribing; a dichotomy mirrored in the overlapping roles of federal and state regulation.[32] Ultimately, federal agencies regulate drug advertising and prescribing, while states are the primary regulators of telemedicine.[33]

Three federal agencies play a potential role in the regulation of platform advertising and prescribing: the Federal Drug Administration (FDA), which regulates prescription drug advertising; the Federal Trade Commission (FTC), which regulates over-the-counter (OTC) drug advertising; and the Drug Enforcement Agency (DEA), which regulates online prescribing.[34] Currently, none of these agencies have asserted jurisdiction over the regulation of

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[28] *Understanding Unapproved Use of Approved Drugs "Off Label"*, FOOD AND DRUG ADMIN., https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label [https://perma.cc/59ZS-PCRG] (last updated Feb. 5, 2018); *see also* FOOD AND DRUG ADMIN., DRUG APPROVAL PROCESS 1–2, https://www.fda.gov/media/82381/download [https://perma.cc/F3A8-GM3M]; Wendy Teo, *FDA and the Practice of Medicine: Looking at Off-Label Drugs*, 41 SETON HALL LEGIS. J. 305, 312 (2017).

[29] Teo, *supra* note 28, at 312.

[30] *Id.* Numerous arguments support and oppose the off-label use of drugs, but these fall outside the scope of this Note. For a discussion of concerns about off-label use and current regulations thereof, see, for example, Bitzer, *supra* note 4, at 186–91; Teo, *supra* note 28, at 316–19; Nathan Cortez, *The Statutory Case Against Off-Label Promotion*, 83 U. CHI. L. REV. ONLINE 124, 128–36 (2016–2017); Fazal Khan & Justin Holloway, *Verify, Then Trust: How to Legalize off-Label Drug Marketing*, 117 PENN ST. L. REV. 407, 425–30 (2012).

[31] For example, Hers advertises propranolol—a drug approved to treat high blood pressure—for performance anxiety. *Propranolol*, HERS, https://www.forhers.com/well-being/propranolol [https://perma.cc/2DMS-DDEK] (noting that "Propranolol is not FDA-approved for the treatment of performance or other anxiety.") (last visited May 8, 2024). *See also, Propranolol for Anxiety: How to Ease Performance Nerves*, KICK (Sept. 2018), https://www.gokick.com/guides/anxiety/propranolol [https://perma.cc/C4CT-GAJP] ("Propranolol is an FDA-approved medication, but prescriptions for situational anxiety are off-label.").

[32] *See* Bitzer, *supra* note 4, at 167–68.

[33] *See infra* Part II.B.

[34] 21 U.S.C. § 352; 15 U.S.C. §§ 52–57; 21 U.S.C. §§ 801–904; Ryan Haight Online Pharmacy Consumer Protection Act, 21 U.S.C. § 829 (2008).

platforms since platforms purport not to be pharmaceutical companies or online pharmacies, but rather telemedicine intermediaries.[35]

By contrast, state bodies are the primary regulators of telemedicine. Organizations such as the American Medical Association (AMA) offer general guidelines for the practice of telemedicine, and state medical boards promulgate regulations.[36] State governments further impose civil and/or criminal penalties for unlawful provider conduct.[37] And while each state's telemedicine laws differ, they generally contain regulations pertaining to licensing, reimbursement, establishing the patient-provider relationship, online prescribing, and informed consent.[38] Platforms remove themselves from state telemedicine regulations by disclaiming the provision of medical services and advice.[39] Instead, they claim to function as middlemen, connecting subscribers to healthcare services and placing the onus of medical care on contracted, third-party doctors.[40] In doing so, the platforms deny engagement in the practice of medicine.[41] Any regulation by states, therefore, falls squarely on the third-party doctor who assumes the responsibility of patient care through contracts with platforms.[42]

To further complicate the regulatory framework, state laws play a large role in regulating online prescribing. States may impose laws that are stricter or more liberal than the federal Controlled Substances Act (CSA), and states may

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[35] The "Practice of Medicine Exception" is inferred from legislative history which suggests that Congress did not intend for the FDA to regulate healthcare providers' in their professional discretion. CAROL R. BERRY, THE DIVIDING LINE BETWEEN THE ROLE OF THE FDA AND THE PRACTICE OF MEDICINE: A HISTORICAL REVIEW AND CURRENT ANALYSIS 2 (1997). Many scholars have discussed this so-called regulatory gap. *See generally* Bitzer, *supra* note 4; Teo, *supra* note 28; Donohue, *supra* note 15.

[36] Terrey L. Hatcher, *Understanding Telehealth Regulations and Requirements*, RELIAS BLOG (July 2, 2020), https://www.relias.com/blog/understanding-telehealth-regulations [https://perma.cc/ZD4Z-VNR3].

[37] Ryan K. Gorman, *Prescribing Medication Through the Practice of Telemedicine*, 30 S. CAL. INTERDISC. L.J. 739, 742 (2021).

[38] *Id.*

[39] *See, e.g.*, *Kick Terms of Use*, KICK, https://www.gokick.com/terms/ [https://perma.cc/S5GA-NHBR] ("The Providers are independent of Kick.") (last visited May 8, 2024); *Terms & Conditions*, NURX, https://www.nurx.com/terms-conditions/ [https://perma.cc/U9K3-ABFF] (visited May 8, 2024) (explaining that medical providers are "independent professionals contracted or employed with affiliated professional entities that coordinate with Nurx"); *Hims & Hers Terms and Conditions*, HIMS HEALTH, https://www.hims.com/terms-and-conditions [https://perma.cc/2MC9-WAA4] (visited May 8, 2024) (noting that Hims & Hers contract with third-party medical providers).

[40] *See* KICK, *supra* note 39; NURX, *supra* note 39; HIMS HEALTH, *supra* note 39.

[41] The "practice of medicine" is a vague concept that describes the delivery of medical services by authorized medical personnel. *See* Teo, *supra* note 28, 306–07. Most states broadly define the practice of medicine as the diagnosis of a disease or condition and subsequent treatment. *Id.* at 307.

[42] *See* James O'Reilly & Amy Dalal, *Off-Label or Out of Bounds? Prescriber and Marketer Liability for Unapproved Uses of FDA-Approved Drugs*, 12 ANNALS OF HEALTH L. 295, 299 (2003).

regulate online prescriptions of uncontrolled substances, which the CSA does not regulate.[43] One survey compared each state's online prescribing laws along three metrics: (1) what the state requires to establish a patient-provider relationship, (2) the state's definition of telemedicine, and (3) which drugs the state prohibits providers from prescribing via telemedicine.[44] It found that states vary widely in their liberality regarding online prescribing via telemedicine.[45]

In short, the potpourri of legislation and bifurcated jurisdiction between the federal and state governments has left holes in the regulatory scheme. And in determining how to close those gaps, legislators must weigh the benefits and costs of imposing more regulations on platforms.

C. *The Benefits and Costs of Regulation*

Platforms form part of a larger movement toward digitally enabled healthcare.[46] Because the platform model operates remotely, it offers various potential benefits, such as lower healthcare costs, greater access to care, and patient self-determination.[47] Many platforms waive consultation costs, copays, and insurance requirements, can be accessed virtually from any location, and seek to give users more autonomy over their treatment options.[48]

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[43] *See generally* Gorman, *supra* note 37; 21 U.S.C. §§ 801–904; *The Controlled Substances Act*, DEA, https://www.dea.gov/drug-information/csa [https://perma.cc/7S8D-BEYW] (last visited May 8, 2024).

[44] Gorman, *supra* note 37, at 755–57.

[45] *Id.* at 757–63.

[46] AM. MED. ASS'N, RETURN ON HEALTH: MOVING BEYOND DOLLARS AND CENTS IN REALIZING THE VALUE OF VIRTUAL CARE 1, 7–8 (2021).

[47] For a more detailed discussion of the potential benefits of platforms see Bitzer, *supra* note 4, at 167 (describing the platform model as "convenient, discreet, and efficient"); Gagne & Helm, *supra* note 4 (explaining that Hims was created to improve health outcomes); NORC, *New Survey Finds Large Number of People Skipping Necessary Medical Care Because of Cost*, NORC UNIV. OF CHI. (March 26, 2018), https://www.norc.org/NewsEventsPublications/PressReleases/Pages/survey-finds-large-number-of-people-skipping-necessary-medical-care-because-cost.aspx [https://perma.cc/ALK4-UWSZ] (demonstrating that reduced healthcare costs may increase healthcare utilization); Ventola, *supra* note 26, at 672 (showing that directly presenting patients with treatment options, rather than leaving it to practitioners, encourages patient accountability); Nathaniel M. Lacktman, *Episode 4: Direct to Consumer (DTC) Telehealth: Does the Industry Need More Regulation?*, FOLEY & LARDNER LLP, at 07:00 (Dec. 11, 2019), https://www.foley.com/insights/publications/2019/12/dtc-telehealth-does-industry-need-more-regulation/ [https://perma.cc/TNV6-DE5M] (explaining that as technology advances, consumers prefer technology-based solutions).

[48] *See, e.g.*, *Our Story*, HIMS, https://www.hims.com/advocacy [https://perma.cc/9R4N-LXCV] (last visited May 8, 2024) ("No copays, high drug prices, long wait times, or inflexible scheduling.");*Expert Care, Delivered*, NURX, https://www.nurx.com/ [https://perma.cc/8YNU-ML8B] (explaining the remote nature of the services); *Letter from Founders*, RO, https://ro.co/founder-letter/ [https://perma.cc/2SDT-5HR2] ("We see a world in which patients are in complete control of their care.").

However, at the time of writing, platforms largely function without meaningful regulation by states or by federal agencies.[49] Most platforms are structured to allow patients to browse the platform's website, choose a medication, and then ask a doctor for approval.[50] This model redesigns the typical physician-patient interaction wherein *doctors* suggest a treatment plan (which may or may not include a prescription), and only then does the patient make a final decision.[51] Thus, inappropriate or over-prescribing, adverse drug events, and legal liability—especially where a platform's and a doctor's goals differ—are potential consequences.[52] Indeed, various medical professionals and the public have called for stricter regulations on platforms engaged in telemedicine.[53] In determining how to meaningfully regulate platforms, legislators must, of course, weigh the benefits and drawbacks of platforms. But more than that, federal and state regulators must diagnose *who* should regulate and *how*. This Note argues that state legislators should pass new legislation to tighten online prescribing regimes that platforms cannot circumvent.

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[49] *See generally* Bitzer, *supra* note 4.

[50] *See supra* notes 7–8 and accompanying text.

[51] *See* Donohue, *supra* note 15, at 668–69.

[52] For a more detailed discussion of the potential drawbacks of platforms see Gagne & Helm, *supra* note 4 (explaining that platform doctors spend only minutes reviewing patient files before deciding whether to prescribe); Bitzer, *supra* note 4, at 191–97 (highlighting the dangers of off-label prescribing); Tewodros Eguale et. al, *Association of Off-label Drug Use and Adverse Drug Events in an Adult Population*, 175 JAMA INTERNAL MED. 55, 55 (2016) (demonstrating the association between off-label use and adverse drug events); Hoffman, *supra* note 24, at 241–42 (noting "the potential for overprescribing and inappropriate prescribing."); Jowa (Zhuo) Shi & Ateev Mehrotra, *Inappropriately Prescribed Antibiotics Will Likely Accompany the Winter Surge of Covid-19*, STAT (Nov. 9, 2020), https://www.statnews.com/2020/11/09/antibiotics-inappropriate-prescribing-winter-surge-covid-19/ [https://perma.cc/MB6V-75PM] (noting the tendency of doctors to err on the side of prescribing medication to avoid liability for failure to prescribe); Suzanne G. Bollmeier, Emily Stevenson, Patrick Finnegan & Scott K. Griggs, *Direct to Consumer Telemedicine: Is Healthcare from Home Best?*, 117 MO. MED. 303, 307 (July/Aug. 2020) ("[Platforms] target their questionnaire to screen for patients who cannot take the medication(s) they offer, rather than investigating the best possible treatment for that patient's medical need.").

[53] *See, e.g.*, Rebecca Robbins, *A Startup Wants Nervous People to Get an Anxiety Pill from an App Before They Have to Give a Speech*, INSIDER (Oct. 25, 2017), https://www.businessinsider.com/startup-wants-to-create-platform-for-nervous-people-to-get-prescriptions-2017-10 [https://perma.cc/3XZ9-3HMU]; Defino, *supra* note 14 ("[T]his is not the right way to market drugs."). Some worry that platforms depict normal conditions as diseases by using misleading advertisements. *See, e.g.*, Brown & De Vynck, *supra* note 12 ("What [platforms] do is suggest a normal pathology is a sickness."); Bollmeier, Stevenson, Finnegan & Griggs, *supra* note 52, at 304 (explaining that platforms advertise "common nonemergency conditions" as illnesses). Others fear patient self-diagnosis. *See* Bollmeier, Stevenson, Finnegan & Griggs, *supra* note 52, at 307.

III. DUAL-LEVEL LEGISLATIVE ACTION TO CREATE MEANINGFUL PLATFORM REGULATION

Digitally enabled healthcare holds the potential to improve quality, reduce costs, and increase access.[54] However, as society moves toward an integrated healthcare system—harmonizing in-person and virtual care delivery models—certain legal parameters are necessary to ensure that information promulgated about treatment options is truthful and that healthcare providers correctly diagnose and treat patients. Given the middleman nature of online DTC telemedicine platforms—serving as a conduit between drug manufacturers and prescribing doctors—regulators must strike a careful balance.[55] On the one hand, platforms must be accountable for their advertising efforts. On the other, both doctors and platforms must be insulated from frivolous litigation to ensure that patients who need medication can access and obtain it.

Because platforms can presently avoid medical liability by contracting with independent doctors, one could argue that actions for adverse events should be brought against the doctors who prescribe the medication. However, as discussed in Part II.C., the platform model inverts the typical physician-patient relationship.[56] Patients approach doctors via platforms, not necessarily for diagnosis and treatment recommendations; they approach doctors with their treatment plans in mind.[57] Thus, there must be a meaningful distinction between claims arising from *platform*-instigated advertising misinformation (claims on the front-end) and claims arising from *doctor*-instigated malpractice (claims on the back-end). Doctors need not, and should not, be implicated in lawsuits related to adverse events resulting from DTC platform advertising. Medical malpractice lawsuits are the existing mechanism for patients to seek redress for injuries by doctors.[58] Application of federal consumer protection laws by the FDA or FTC, therefore, should be limited to providing a mechanism of redress against platforms.

In practice, regulating platforms should entail a two-part approach involving both federal and state law. To significantly oversimplify the federal regulatory scheme, the FDA regulates prescription drug promotion and drug labeling whereas the FTC regulates OTC drug promotion.[59] Based on the statutes from which each derives its regulatory authority, it is not completely clear which agency could or should assume responsibility for regulating DTC online

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[54] *See* AM. MED. ASS'N, RETURN ON HEALTH: MOVING BEYOND DOLLARS AND CENTS IN REALIZING THE VALUE OF VIRTUAL CARE 1, 7–8 (2021).

[55] Platforms should seek to extend access to quality primary care, not replace it. *See, e.g.*, Lacktman, *supra* note 47, at 11:05.

[56] *Supra* notes 50–51 and accompanying text.

[57] *See supra* note 7 and accompanying text.

[58] *See generally* B. Sonny Bal, *An Introduction to Medical Malpractice in the United States*, 467 CLINICAL ORTHOPEDICS AND RELATED RSCH. 339 (2009).

[59] Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. §§ 301–92 (Suppl. 5 1934); 15 U.S.C. §§ 52–57.

telemedicine platforms.[60] What is clear is that neither has.[61] Rather than belabor the merits or methods of federal regulation of platform advertising, this Note focuses primarily on revisions to state telemedicine laws.[62] States should tighten telemedicine laws so that increased access to care remains, but adequate patient consultations are prioritized.

States regulate telemedicine with varying levels of restrictiveness.[63] In any case, state-level legislation that regulates uncontrolled substances, acting as an analog to the CSA and Ryan-Haight Act (RHA), is necessary. The CSA regulates the prescription and use of controlled substances while the RHA seeks to prevent illegitimate online prescription of controlled substances.[64] State laws can restrict the prescription of controlled substances more than the RHA, and indeed some do.[65] However, no comprehensive scheme exists to regulate the prescription of uncontrolled substances.[66] Although the federal government could enact nationwide legislation to regulate the prescription of uncontrolled substances via telemedicine, it is better left to state legislatures, which hold the power to protect the public health and safety of their citizens.[67] Moreover, each state has a medical practice act that circumscribes the practice of medicine in the state and allows state medical boards—which "have historically been the watchdogs of the medical practice"— to oversee physician conduct.[68] Not to

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[60] *See* Bitzer, *supra* note 4, at 191–97; *see also* U.S. FOOD & DRUG ADMIN., FDA-225-71-8003, MEMORANDUM OF UNDERSTANDING BETWEEN THE FEDERAL TRADE COMMISSION AND THE FOOD AND DRUG ADMINISTRATION (1971), https://www.fda.gov/about-fda/domestic-mous/mou-225-71-8003 [https://perma.cc/2F32-DTVD].

[61] *See generally* Bitzer, *supra* note 4.

[62] For more information on federal regulation of platform advertising, see generally Bitzer, *supra* note 4.

[63] *See supra* notes 43–45 and accompanying text; *see also Online Prescribing*, CTR. FOR CONNECTED HEALTH POL'Y, https://www.cchpca.org/topic/online-prescribing/ [https://perma.cc/S2AK-NDEP] (last visited Mar. 18, 2024).

[64] Controlled Substances Act, 21 U.S.C. §§ 801–904; Ryan Haight Online Pharmacy Consumer Protection Act, 21 U.S.C § 829 (2008).

[65] Gorman, *supra* note 37, at 762–63. Generally, the federal government has disclaimed regulation of the practice of medicine, which means that there are no express or implied preemption issues regarding state telemedicine laws. *See, e.g.*, 42 U.S.C. § 1395.

[66] *See Online Prescribing*, *supra* note **Error! Bookmark not defined.**; *see also* Gorman, *supra* note 37, at 763–65.

[67] *See* U.S. Const. amend. X; *see also* Berman v. Parker, 348 U.S. 26, 32 (1954).

[68] Jacqueline Landees, *State Medical Boards, Licensure, and Discipline in the United States*, 14 AM. PSYCH. PUB. 337, 337–38 (2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7011294/ [https://perma.cc/H2WT-MLD7]; *see* Gabrielle A. Vance, *The Hoosiers Got It Wrong: The Need for States to Enact Stricter Prescribing Regulations via Telemedicine Services*, 12 WM. & MARY BUS. L. REV. 221, 225 n.23 (2020). Congress's authority to enact the CSA was the Commerce Clause. *See* U.S. Const. Art. I, § 8. Although Congress could pass a law that regulates prescribing and/or the use of uncontrolled substances, national legislation is not the most effective way to regulate telemedicine prescribing. State governments and medical boards are situated more closely to prescribing providers and can more immediately deal with regulatory and disciplinary shortcomings. Robert Moffit, *Health Care Reform: Why State Officials Should*

mention, most state legislatures have given their medical boards the same tools as federal agencies to punish doctors by suspending or revoking medical licenses, or imposing fines.[69]

State laws aimed at monitoring online prescribing of uncontrolled substances should do two things: (1) make in-person intake visits the default and (2) explicitly define what an "appropriate" or "sufficient" examination entails.

A. *States Should Require In-Person Intake Visits*

In-person intake visits for uncontrolled substances strikes the appropriate balance between access to care and patient protection. States must start by considering what types of uncontrolled substances physicians can safely prescribe via online platforms without in-person evaluations and legislate accordingly.[70] Tightened prescribing regimes should, for example, disallow the online prescription of medications pertaining to the heart, mental health, or other serious conditions absent an in-person evaluation.

But regimes should not be so restrictive as to prohibit the online prescription of medications altogether. Indeed, physicians can likely prescribe medications such as birth control without an in-person evaluation, as it poses fewer severe side effects.[71] And once a provider has evaluated a patient in-person, states should allow telemedicine visits for follow-up appointments or routine patient monitoring to increase access to healthcare. To be sure, requiring an in-person visit may decrease access to healthcare in some instances, but striking the proper balance with competent medical care is important to avoid malpractice-related liability and achieve long-term positive health outcomes. In-person visits verify that a patient-provider relationship exists (which triggers the physician's legal duty to render competent care) and permit more thorough patient consultations (which often means more accurate diagnoses and treatment).[72]

B. *States Should Clarify the Meaning of an "Appropriate" Patient Examination*

State legislation that defines the standards of an "appropriate" or "sufficient" intake examination is another way to balance access to healthcare

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Take the Lead, HERITAGE FOUND. (Jan. 24, 2018), https://www.heritage.org/health-care-reform/report/health-care-reform-why-state-officials-should-take-the-lead [https://perma.cc/5XV2-XBA8].

[69] *See, e.g.*, STATE MED. BRD. OF OHIO, DISCIPLINARY & FINING GUIDELINES, (2020).

[70] No state specifies what form of telemedicine service is required for the specific drug being prescribed. Vance, *supra* note 68, at 244. For further discussion of state telemedicine laws related to online prescribing of uncontrolled substances see generally *id.*

[71] *See* Danielle B. Cooper, Preeti Patel & Heba Mahdy, *Oral Contraceptive Pills*, STATPEARLS, https://www.ncbi.nlm.nih.gov/books/NBK430882/ [https://perma.cc/P5YL-FJU3] (Nov. 24, 2022).

[72] *See* Bollmeier, Stevenson, Finnegan & Griggs, *supra* note 52, at 307.

and quality of care. As mentioned, states vary widely in how they regulate uncontrolled substances.[73] Some limit a physician's ability to prescribe uncontrolled substances to a person that a doctor has not evaluated in-person.[74] However, many of those same states have created an exception that allow physicians to prescribe uncontrolled substances if the physician conducts an "appropriate" or a "sufficient" examination.[75] But virtually no state defines or explains what either of these terms require of the physician.[76] Appropriateness and sufficiency are relatively vague concepts. Indeed, one court stated that determining appropriateness resembles "a mutable cloud which is always and never the same."[77] Defining appropriateness in the context of telemedicine is important and may help improve the current balance between regulation and access.

To clarify the appropriateness or sufficiency standards, states can borrow from the Emergency Medical Treatment and Active Labor Act (EMTALA), a federal statute.[78] When a patient enters an emergency department, EMTALA requires hospitals to conduct an "appropriate medical screening examination" to determine whether an emergency medical condition exists.[79] Federal courts have interpreted "appropriateness" to require two elements: (1) the examination must be "reasonably calculated to identify critical medical conditions," and (2) it must provide the same "level of screening uniformly to all who present substantially similar complaints."[80] Although EMTALA involves medical screenings for acute emergency situations, this distinction helps clarify what is important about medical screenings generally—proper identification of medical

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[73] *Online Prescribing*, *supra* note 63; Gorman, *supra* note 37, at 757–63.

[74] *See, e.g.*, S.C. CODE ANN. § 40-47-113 (2023). Other states give providers discretion to decide whether drugs are prescribed via telemedicine services. *See, e.g.*, WYO. HEALTHCARE LICENSING BDS., UNIFORM POLICY FOR THE APPROPRIATE USE OF TELEHEALTH TECHNOLOGIES IN THE DELIVERY OF HEALTHCARE 3, 6–7 ("Prescribing medications, in-person or via telehealth, is at the professional discretion of the provider.").

[75] *See, e.g.*, CAL. BUS. & PROF. CODE § 2242 (West 2019) (noting that prescribing or dispensing dangerous drugs "without an appropriate prior examination . . . constitutes unprofessional conduct."); FLA. STAT. 456.47(2)(b) (2023).

[76] *See, e.g.*, FLA. STAT. 456.47(2)(b) (2023).

[77] Correa v. Hospital of San Francisco, 63 F.3d 1184, 1192 (1st Cir. 1995) quoting, in part, Ralph Waldo Emerson in Essays: First Series (1841).

[78] 42 U.S.C. § 1395dd(a). EMTALA "ensure[s] public access to emergency services regardless of ability to pay." *Emergency Medical Treatment & Labor Act (EMTALA)*, CNTRS. FOR MEDICARE & MEDICAID SRVS., https://www.cms.gov/medicare/regulations-guidance/legislation/emergency-medical-treatment-labor-act [https://perma.cc/R2XU-7JRX] (Jan. 5, 2024).

[79] *Id.*

[80] Del Carmen Guadalupe v. Negron Agosto, 299 F.3d 15, 20 (1st Cir. 2002); *see also* Baber v. Hosp. Corp. of Am., 977 F.2d 872, 879 (4th Cir.1992); Marshall v. E. Carroll Parish Hosp. Serv., 134 F.3d 319, 323–24 (5th Cir. 1998); Cleland v. Bronson Health Care Group, Inc., 917 F.2d 266, 272 (6th Cir. 1990); Summers v. Baptist Med. Ctr. Arkadelphia, 91 F.3d 1132, 1139 (8th Cir. 1996) (en banc); Holcomb v. Monahan, 30 F.3d 116, 117 (11th Cir. 1994); Gatewood v. Wash. Healthcare Corp., 933 F.2d 1037, 1041 (D.C. Cir. 1991).

conditions and uniform treatment across similar situations.[81] Thus, when defining an appropriate screening for telemedicine purposes, states should include language that ensures virtual visits meet the same standards as in-person visits. The essential feature to match would be their level of comprehensiveness, reflected in, for example, the ability of providers to utilize key diagnostic devices and spend sufficient time with patients. Where a reasonable provider would use a physical diagnostic tool or spend several minutes in-person discussing a patient's medical history and current symptoms, state law should require the same of virtual visits offered through platforms. In other words, an in-person intake visit might be necessary.

Iowa has codified standards of practice for telemedicine and provides a useful example of how states can achieve a meaningful balance between patient protection and a physician's ability to practice medicine. The law makes an in-person medical evaluation the default.[82] But it gives doctors the flexibility to conduct virtual medical evaluations and examinations "if the technology utilized in a telemedicine encounter is sufficient to establish an informed diagnosis as though the medical interview and physical examination had been performed in-person."[83] In that way, the law imposes a legal requirement that virtual evaluations meet the same standard as in-person evaluations in terms of the quality of the evaluation. Although the "sufficiency" standard may be difficult to apply in non-routine situations, state medical boards possess the expertise needed to analyze the nuances of any situation giving rise to an investigation or litigation and can help determine whether the legal standard was met.[84]

Iowa's framework has the added benefit of mirroring the two EMTALA requirements. The "sufficiency" provision mirrors the first EMTALA prong: requiring physicians to conduct medical evaluations to identify relevant conditions.[85] Iowa requires that, before proffering treatment (which includes prescribing medications), physicians must, "when medically necessary," conduct an analysis of medical history and a physical examination "sufficient for the diagnosis and treatment of the patient."[86] So, in the context of telemedicine, the consult must be an "adaptive, interactive and responsive online interview."[87] This portion of the statute mirrors EMTALA's second prong: attempting to ensure that entities provide uniform levels of screening to

[81] *See* 42 U.S.C. § 1395dd(a).

[82] IOWA ADMIN CODE r.653-13.11(8) (2024).

[83] *Id.*

[84] *See generally* Landees, *supra* note 68.

[85] *See* 42 U.S.C. § 1395dd(a).

[86] IOWA ADMIN CODE r.653-13.11(8) (2024). The language stating that evaluations are required only "when medically necessary" could include a proviso, listing situations where an evaluation is mandatory. Clarifying where evaluations must be in-person forecloses the opportunity for platforms to pressure doctors into inappropriately prescribing drugs.

[87] *Id.* The law further provides that internet questionnaires composed of "a static set of questions" to which the "patient responds with a static set of answers" are insufficient to meet legal standards. *Id.* Thus, platforms offering services in Iowa must offer at least a live virtual visit.

both in-person and virtual patients presenting substantially similar symptoms or conditions.[88]

It should be noted that in the EMTALA context, an appropriate medical screening "is not judged by its proficiency in accurately diagnosing the patient's illness," but rather to ensure that providers conduct screenings "equitably in comparison to other patients with similar symptoms."[89] This means that a negligent diagnosis by a doctor should not necessarily fall within telemedicine laws. Instead, most states have standard-of-care provisions that govern medical malpractice generally to cover such cases.[90]

When defining appropriateness, state legislatures should also set time floors under which telemedicine visits cannot fall. Lengths of visits can vary, depending on both the condition at issue and whether the visit seeks to establish a patient-provider relationship or functions as a follow-up.[91] For example, at the federal level, Centers for Medicare and Medicaid Services requires that providers spend twenty minutes gathering and analyzing patient information to satisfy the "interactive communication" requirement in order to bill for the visit.[92] Analogous legislation at the state level could alleviate issues of inappropriate prescribing, overprescribing, and compromised medical ethics.[93] Of course, intake visits in which platform subscribers first meet a doctor and establish a patient-provider relationship will require more time than follow-up visits.[94] State legislatures should account for this discrepancy with bifurcated legislation. For example, visit lengths for first-time visits may require a minimum of fifteen to twenty minutes, while follow-up visits may require a minimum of only five to ten minutes.[95] Notably, doctors working in brick-and-mortar healthcare facilities and platforms alike face pressure to see many

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[88] *See* 42 U.S.C. § 1395dd(a).

[89] Fewins v. Granbury Hosp. Corp., 662 F. App'x 327, 330–31 (5th Cir. 2016) (citations omitted).

[90] *See, e.g.*, OHIO REV. CODE § 2305.113 (2023).

[91] Most states have telemedicine laws that describe the proper circumstances for establishing a patient-provider relationship. *See, e.g.*, N.J. REV. STAT. § 45:1-63 (2017); IND. CODE § 25-1-9.5-7(b) (2022). Most laws require the following: provider and patient disclose identities and locations; provider takes the medical history of patient; provider maintains a medical record for the patient. Gorman, *supra* note 37, at 761.

[92] *Final Policy, Payment, and Quality Provisions Changes to the Medicare Physician Fee Schedule for Calendar Year 2021*, CTRS. FOR MEDICARE AND MEDICAID SERVS. (Dec. 1, 2020), https://www.cms.gov/newsroom/fact-sheets/final-policy-payment-and-quality-provisions-changes-medicare-physician-fee-schedule-calendar-year-1 [https://perma.cc/8LEA-9V5G].

[93] *See supra* Part II.C.

[94] *See generally* K.D. Bertakis & E.J. Callahan, *A Comparison of Initial and Established Patient Encounters Using the Davis Observation Code*, 24 FAM. MED. 307 (1992).

[95] First-time visits for mental health diagnoses and treatment can take hours. *See Comprehensive Psychiatric Evaluation for Children*, NATIONWIDE CHILD.'S HOSPITAL https://www.nationwidechildrens.org/conditions/health-library/comprehensive-psychiatric-evaluation-for-children [https://perma.cc/3FAE-46NL].

patients in a short time.[96] Thankfully, doctors have discretion, through the practice of medicine, to adapt to changing pressures.[97] Thus, state legislation in this space should not eliminate a doctor's ability to exercise discretion about the length of visits. Rather, these parameters prevent perfunctory virtual visits and restore the sanctity of the patient-provider relationship.

To be sure, requiring in-person intake visits and extending visit length could nominally decrease utilization of telemedicine and access. But without stricter definitions of appropriateness or sufficiency—which concern how physicians must conduct the medical evaluation and follow-up—platforms have leeway to encourage contracted doctors to rifle through patient consultations and fail to follow up on treatment plans.[98]

Opponents may argue that nationalizing standards of care provides a simpler regulatory route, especially in situations where physicians prescribe across state lines. However, national legislation fails to account for two things. First are general principles of federalism. States retain police powers that allow them to promulgate laws for the benefit of their unique citizens.[99] Second, inter-state licensing compacts promote physician practice across state lines while preserving state sovereignty.[100] To that end, state legislators must carefully balance access and quality care to both limit liability and ensure positive health outcomes. This nuanced, community-level care is something that federal legislation cannot accomplish.

Finally, there is little concern that with more regulation platforms will exit the market. On the contrary, platforms will more likely modify their practices to conform to new requirements affecting their practices. Where states have started to regulate this space, platforms have adapted to the changes without leaving the market. For example, some platforms now offer video conferencing with doctors, rather than relying solely on medical questionnaires, to comply with state telemedicine requirements.[101] Services offered by Hims and Hers, for example, were initially offered in only 28 states, and subscribers were only required to submit an online medical questionnaire which was then analyzed by a third-party doctor.[102] Now, however, Hims and Hers offer real-time physician

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[96] *See* Kriti Prasad, et al, *Time Pressure During Primary Care Office Visits*, 35 J. GENERAL INTERNAL MED. 465, 465 (2019).

[97] *See* Teo, *supra* note 28, at 306–07.

[98] *See* Gagne & Helm, *supra* note 4. One Hims doctor reported that he takes three to five minutes to review a patient's profile, analyzing 15 to 20 profiles an hour. *Id. See also* Bollmeier, Stevenson, Finnegan & Griggs, *supra* note 52, at 307 (arguing that platforms have a financial interest in patients utilizing the drug(s) they promote).

[99] *See* Medtronic, Inc. v. Lohr, 518 U.S. 470, 475 (1996).

[100] *About the Compact*, INTERSTATE MED. LICENSURE COMPACT COMM'N, https://www.imlcc.org/a-faster-pathway-to-physician-licensure/ [https://perma.cc/9JL9-BLUT].

[101] Ruth Reader, *Hims & Hers Is Bringing Its Health Products to All 50 states* (Jan 22, 2020), https://www.fastcompany.com/90453929/hims-hers-is-bringing-its-online-pharmacy-to-all-50-states [https://perma.cc/G9CV-GWNH].

[102] *Id.*

consultations for subscribers in states with more restrictive definitions of telemedicine and regulation of online prescribing.[103]

IV. CONCLUSION

Healthcare is moving increasingly toward digitally enabled care, and online DTC telemedicine platforms play a central role in this trend.[104] Instead of fighting the movement through heightened regulations that stifle the platform model, legislators should implement patient-centered laws that facilitate access through these platforms while maintaining quality of care. At the federal level, FDA or FTC enforcement of rules modeled on the FDA's current advertising scheme to cover platforms would protect consumers from misleading drug promotion. At the state level, new telemedicine laws that explicitly define what constitutes an appropriate telemedicine visit would help ensure patients receive accurate diagnoses and effective treatment plans. Quality healthcare, increased access, and decreased costs are of the utmost importance to providers and patients. Meaningful legislation at the state level facilitates this tripartite goal.

[103] *Id.*; *see also Terms and Conditions*, *supra* note 8 ("Our Service is subject to state regulations and may change from time to time due to changes in applicable regulatory requirements.").

[104] Brown & De Vynck, *supra* note 12 ("It's a trend that's coming right or wrong.").