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Telehealth Companies Sued for Selling Compounded GLP-1 Drugs and Violations of Corporate Practice of Medicine Laws

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ALERTS

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Branded drug manufacturers, including Eli Lilly and Company (Eli Lilly), have been pursuing various legal actions against compounding pharmacies and telehealth companies that provide compounded diabetes and weight-loss drugs, escalating the legal battle after the FDA removed the drugs from the shortage list. Legal claims raised by the branded drug manufacturers under federal laws have included the Lanham Act and the Federal Food, Drug, and Cosmetic Act (FDCA). In the latest series of lawsuits brought on April 23, 2025, Eli Lilly asserted that the telehealth companies violated the Lanham Act and California laws by engaging in unfair, deceptive, false, and misleading advertising and practices over the safety, effectiveness, and quality of the compounded drugs. Additionally, for the first time in this line of cases, Eli Lilly also asserted that the telehealth companies violated California's corporate practice of medicine (CPOM) laws.

Specifically, Eli Lilly sued the two telehealth companies and their affiliates for, among other things:

- engaging in the unlicensed practice of medicine by allowing unlicensed persons, such as founders, officers, and management companies, to influence medical decisions;
- prescribing and altering GLP-1 drug formulations and dosages without prior physician exam or medical justification; and
- making decisions for patients based on financial gain rather than on clinical need.

These lawsuits are significant as they signal a more aggressive posture toward companies that fail to rigorously monitor CPOM compliance, while also intensifying scrutiny on private equity and venture capital investments in healthcare MSOs. The lawsuits may also accelerate and be cited as justification for California's legislative push for greater oversight of MSOs and PCs, a development the industry is already watching closely. The lawsuits underscore the need for proactive CPOM compliance reviews before private investment and highlight that a legally sound CPOM structure is essential for attracting capital and scaling in digital health.

Key CPOM and FDA Takeaways and Recommendations

Telehealth companies must comply with applicable CPOM laws and regularly evaluate their compliance.

- Typically, telehealth companies seeking to protect medical decision-making and comply with CPOM laws utilize a management services organization (MSO) and professional corporation (PC) model (MSO-PC model).
- A vital part of compliance with the MSO-PC model is ensuring that PC owners comply with applicable state PC laws, including maintaining active licenses, and that they control all medical decision-making.

- PCs must be owned and controlled by actively licensed professionals. Many states, such as California, require that such professionals be actively licensed in the state. Other states simply require that such professionals are actively licensed in one or more states.
- Telehealth companies should have a process for verifying and maintaining all professional licenses held by PC owners, employees, contractors, and agents. Similarly, investors and partners should verify licensure status as part of any due diligence before entering into a transaction or agreement.
- Establishing an MSO-PC model is just the start—ongoing compliance with CPOM requires regular reviews and adjustments of policies and procedures to ensure that the legal boundaries are observed.
- See our recent client advisory for additional information.

Telehealth companies that provide patient care and/or prescribe medications must ensure that medical decisions, including decisions about prescriptions, are made solely by licensed medical professionals and are free from the influence or control of corporations or unlicensed persons.

- Decisions that may affect the type of medications a telehealth company can obtain for patients should be made solely by the PC, together with its licensed medical professionals, to ensure that the change will work for patients and that it can be communicated to patients in advance to ensure patients have time to find alternative care, if necessary.
- Changes to patient medications, treatment plans, or protocols should involve a prior medical examination, where appropriate, and should be guided by measurable medical indications for the modifications, in the licensed provider's judgment.
- All communications with patients regarding medical decision-making, such as questions about or adjustments to medications, should be answered by medical professionals. Under no circumstances should such questions be answered by unlicensed employees of the MSO.
- While the MSO can facilitate the communication between patients and their treating clinicians by providing non-clinical administrative support services, the MSO should not direct or otherwise unduly influence the autonomy of patients and clinicians.

Telehealth companies marketing or selling compounded products should verify:

- their compounding pharmacies and outsourcing facilities compound in accordance with the requirements and limitations under Sections 503A and 503B of the FDCA, as well as the FDA's policies for compounding drug products that are no longer on the drug shortage list; and
- their advertisements and promotional materials are truthful and not misleading to consumers.

Overview of the CPOM Allegations Against Mochi Health and Fella Health

Two complaints were filed by Eli Lilly against telehealth companies on April 23, 2025:

- One was filed against Mochi Health Corp. (Mochi Health), its professional corporation (PC) affiliates Mochi Medical CA P.C. (Mochi Medical CA) and Mochi Medical P.A. (Mochi Medical FL), and its compounding pharmacy affiliates. We will refer to this lawsuit as the "Mochi Health Complaint."
- The other was filed against Aios Inc. (Fella Health) and its PC affiliates Fella Medical Group P.A. (Fella Medical FL) and Fella Medical Group P.C. (Fella Medical CA). We will refer to this lawsuit as the "Fella Health Complaint."

Mochi Health and Fella Health operate similar telehealth companies that market or sell compounded versions of Eli Lilly's GLP-1 drugs, and the Mochi Health Complaint and the Fella Health Complaint contain similar facts and allegations. Both companies appear to utilize an MSO-PC model wherein the MSO (an unlicensed corporation) provides a telehealth platform that consumers can visit to be connected with a medical professional who determines whether the consumer is eligible for medication and, if so, writes them a prescription. In a compliant MSO-PC model, all medical professionals are employed or contracted by the PC, and the PC maintains full autonomy and authority over medical decision-making, including the type and contents of any prescriptions issued by medical professionals. In Eli Lilly's complaints against Mochi Health and Fella Health, however, Eli Lilly alleges that this boundary was crossed, and both Mochi Health and Fella Health exerted undue influence and control over medical decision-making.

The Mochi Health Complaint[1]

The Mochi Health Complaint alleges that Mochi Health repeatedly violated California's CPOM laws "by influencing the dosing and formulation of compounded tirzepatide." According to the complaint, this

included allegedly switching patients to doses with additives and non-standard doses for Mochi Health's financial reasons as opposed to clinically indicated reasons. Notably, the Mochi Health Complaint asserts these decisions were made and orchestrated by Mochi Health, an unlicensed corporation, as opposed to the Mochi Health PCs, which appear to be owned by a licensed medical professional. Under California law, such decisions must be made by medical professionals, free from the influence or control of corporations or unlicensed persons. Further, the complaint alleges that the switches to doses with additives and non-standard doses were not supported by patient exams or medical indications. Instead, the Mochi Health Complaint alleges these alterations were made solely for Mochi Health's financial gain.

The Fella Health Complaint[2]

The Fella Health Complaint alleges that Fella Health violated California's CPOM laws by providing medical advice to patients through its unlicensed founders, officers, and personnel. The complaint alleges several instances when Fella Health's non-physician personnel advised patients on medication doses and side effects and implied that they could adjust patient prescriptions, without mentioning the need for medical input. Similar to the Mochi Health Complaint, the complaint also alleges that Fella Health would switch patients to doses with additives and non-standard doses for Fella Health's financial reasons as opposed to clinically indicated reasons. Last, the Fella Health Complaint alleges that patient exams or medical indications did not support any medication changes made by Fella Health.

Why Are These Suits Significant?

These lawsuits could have significant implications for telehealth companies, including: i) establishing a playbook for third parties looking to sue telehealth companies for violations of California's CPOM laws; ii) establishing precedent for damages and awards, if any, a third party might receive for such claims; and iii) triggering increased oversight and enforcement of California's CPOM laws from various California agencies, including the Medical Board of California and the California Attorney General.

These lawsuits may also increase legislators' attention and focus on California's CPOM (and related) laws. Last year, California Governor Gavin Newsom vetoed a bill that would have added an oversight mechanism for certain healthcare investments. Earlier this year, California introduced legislation to restrict the influence of private equity in healthcare (AB 1415) and bolster the state's CPOM enforcement capabilities (SB 351). Given the state's increased interest in CPOM, it's possible that these suits may spur even more CPOM-related proposals in the next legislative cycle.

Contact Us

If you'd like to learn more about the corporate practice of medicine, please see our recent client advisory. Wilson Sonsini will continue to closely monitor the development of these cases in California and FDA enforcement activity involving compounded GLP-1 drug products.

For more information, please contact Wilson Sonsini attorneys Andrea Linna, Eva Yin, Nawa Lodin, Jonathan Trinh, Seamus Taylor, or any member of Wilson Sonsini's Digital Health or FDA Regulatory, Healthcare, and Consumer Products practice groups. For guidance regarding litigation involving GLP-1 drug compounding, please contact a member of the Patent Litigation practice group.

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[1] Compl., *Eli Lilly and Co. v. Mochi Health Corp. et al.*, No. 3:25-cv-03534 (N.D. Cal. 4/23/25).

[2] Compl., *Eli Lilly and Co. v. Aios Inc et al.*, No. 3:25-cv-03535 (N.D. Cal. 4/23/25).