GLP-1 COMPOUNDING UNDER FIRE:

LEGAL, REGULATORY, AND COMPLIANCE RISKS FOR PHARMACIES, TELEHEALTH PLATFORMS AND PRESCRIBERS

By Arielle Miliambro and Martha Rumore

As semaglutide, tirzepatide, and other GLP-1 medications continue to dominate the weight management and diabetes markets, the legal and regulatory landscape surrounding compounded GLP-1s is rapidly evolving—and becoming significantly more complex. Manufacturers, regulators, and pharmacy benefit managers (PBMs) are exerting increasing pressure on compounders, prescribers, and telehealth platforms, raising urgent compliance concerns.

Frier Levitt attorneys outline below the current state of GLP-1 compounding, enforcement trends, and emerging legal risks healthcare stakeholders must navigate.

GLP-1 COMPOUNDING AT A LEGAL CROSSROADS

GLP-1 compounding is under unprecedented scrutiny. Following preliminary injunction rulings favoring manufacturers, federal courts have found that semaglutide and tirzepatide are no longer in sufficient shortage to justify compounding 'essentially a copy. Compounders may still prepare GLP-1s, but only under strict criteria—formulations must not be "essentially a copy" and must demonstrate a clinical difference for an individual patient (e.g., adding pyridoxine to reduce nausea).

At the same time, major drug manufacturers like Novo Nordisk and Eli Lilly have filed lawsuits across more than 30 states, alleging that compounded GLP-1 products are mass manufactured without individualized medical need. Several of the most recent cases challenge the very foundation of 503A compounding by disputing claims of patient-specific necessity.

PBMS AND INSURERS ARE RESHAPING ACCESS AND REIMBURSEMENT

Despite surging demand, insurance coverage for GLP-1s remains limited. Most group health plans do not cover these drugs for weight loss, and 2025 has seen a *decline* in coverage even as utilization grows. Insurers cite cost concerns but are reevaluating policies under pressure from employers and patients.

Meanwhile, PBMs are aggressively negotiating rebates and driving formulary changes. Recent shifts, such as CVS Caremark removing Zepbound in favor of Wegovy, demonstrate the PBMs' influence. However, reimbursement for pharmacies remains critically low—surveys show that the majority of independent pharmacies lose money on each GLP-1 prescription due to acquisition costs exceeding insurer payments.

LEGAL RISKS FOR TELEHEALTH PLATFORMS AND CPOM VIOLATIONS

In addition to reimbursement and access challenges, compounders and prescribers face growing liability from *corporate practice of medicine* (CPOM) violations. Recent litigation filed by Eli Lilly targets telehealth companies for allegedly allowing non-clinicians to direct patient care and treatment protocols. In several states—including California and New Jersey—such structures are prohibited, and violations can result in license suspension, civil liability, or even criminal charges.

Many telehealth platforms were formed in states with relaxed rules and now serve patients nationwide. However, compliance must align with the laws where the *patient* resides—not just the entity's home state. Physicians working for these platforms, even part-time, are at risk if they are not operating through compliant models.

COMPLIANCE PRIORITIES FOR STAKEHOLDERS

Given the increasing litigation and regulatory scrutiny, stakeholders must take proactive steps:

- **Evaluate Business Structures**: Ensure medical services are provided through entities compliant with state CPOM laws.
- **Separate Clinical from Administrative Functions**: Use proper MSO models to avoid regulatory overreach and protect provider independence.
- **Review Marketing and Web Content**: Language around GLP-1s must comply with FDA, FTC, and trademark laws—many companies have already pulled down ads or scrubbed sites.
- **Ensure Individualized Treatment**: Prescriptions should reflect real clinical judgment, not pre-set protocols designed to circumvent FDA guidelines.

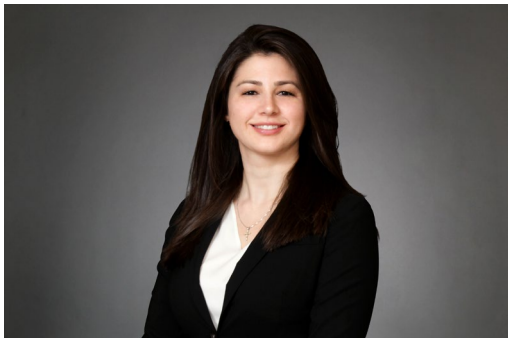
LOOKING AHEAD: THE FUTURE OF GLP-1 THERAPIES

The compounded GLP-1 market faces additional headwinds:

- **New Formats**: Compounded products combining GLP-1s with ingredients like B12 or glycine are under increasing scrutiny for alleged lack of medical necessity.
- **Oral Formulations**: An oral semaglutide product may hit the market by late 2025, posing new competition for injectables.
- **Obesity Discrimination Lawsuits**: Legal challenges are underway in states like Washington and Maine over exclusions of GLP-1s from health plans under anti-discrimination statutes.
- **Legislative Gaps**: While the Treat and Reduce Obesity Act seeks Medicare Part D coverage for anti-obesity drugs, CMS has yet to adopt such proposals for 2026.

CONCLUSION

GLP-1 therapies represent a groundbreaking advancement in obesity and diabetes care, but the compounded market is being squeezed by legal, regulatory, and financial forces. Pharmacies, telehealth companies, and clinicians must act now to assess compliance, mitigate risk, and adapt to a shifting—and increasingly litigious—landscape.



Arielle Miliambro is a partner in Frier Levitt's Healthcare and Life Sciences Departments with a focus on regulatory and transactional law. Arielle is a trusted advisor for pharmacy clients offering support on range of issues including remote prescription processing, central fill arrangements, compounding pursuant to 503A/503B, and compliance with hub models and manufacturer rebate programs. She also assists with licensing board matters, such as audits, preliminary investigations, and disciplinary proceedings, and provides support for pharmacy acquisitions and sales.

Martha Rumore, PharmD., Esq., MS, LLM, FAPhA is a pharmacist-attorney in Frier Levitt's Life Sciences Department. Dr. Rumore focuses on Pharmacy and Healthcare Law, pharmaceutical and medical device intellectual property including all aspects of trademark and patent law as well as Food, Drug & Cosmetic Law. She represents pharmacy compounding clients in a myriad of regulatory compliance issues ranging from FDA inspections to state board of pharmacy matters to PBM audits. She has 20 years of law firm experience in the area of Food, Drug & Cosmetic Law, and pharmaceutical intellectual property, especially generic pharmaceuticals.