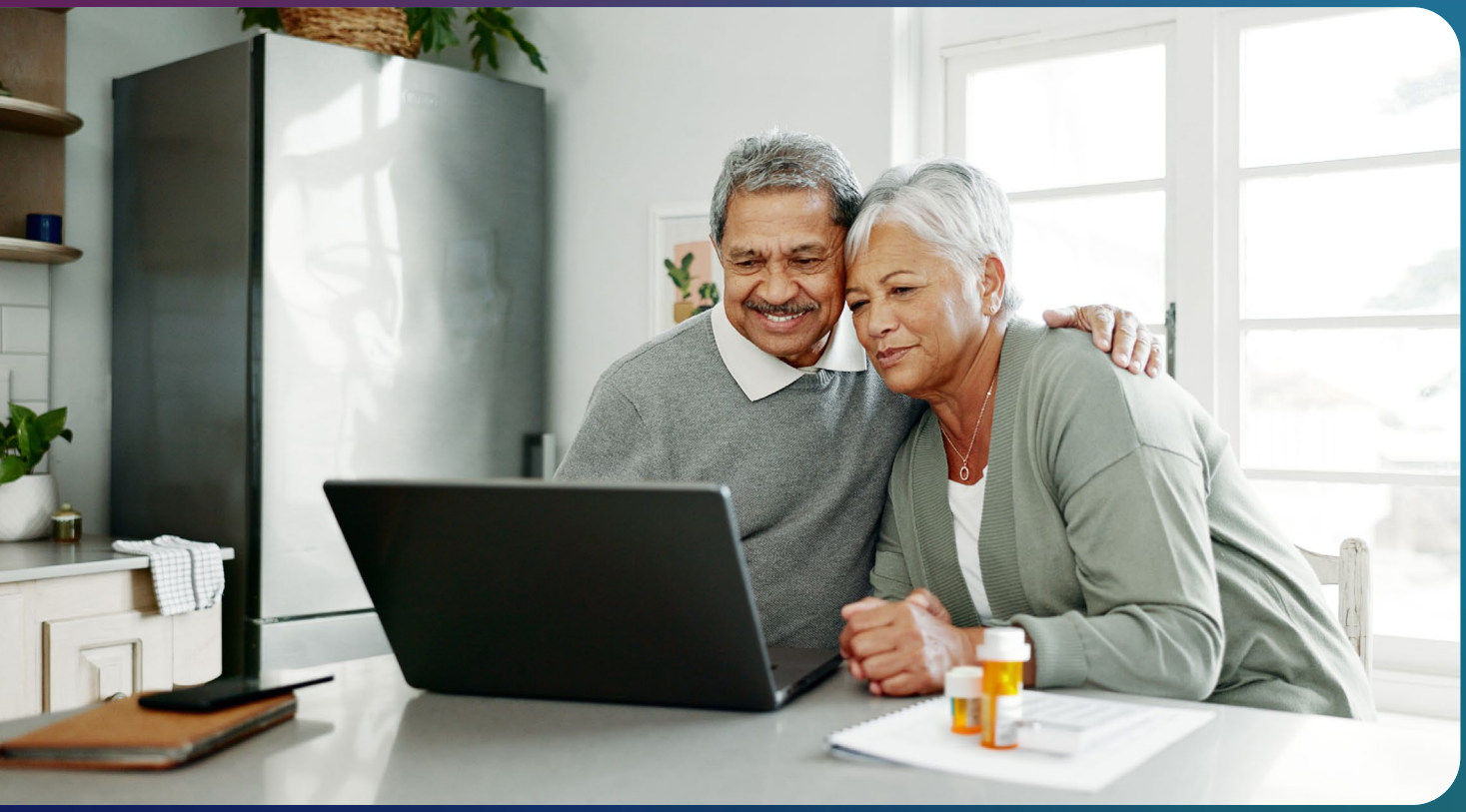
SHIELDS
HEALTH SOLUTIONS



WHITE PAPER

Click, Prescribe, Deliver: The New Era of Direct-to-Consumer Pharmaceutical Care

Introduction

As the healthcare landscape rapidly evolves, challenges related to medication access and affordability come to the forefront. Technology driven solutions, such as the direct-to-consumer (DTC) pharmaceutical care model, have emerged to address these challenges. This model allows patients to obtain prescription medications—including glucagon-like peptide-1 receptor agonists (GLP-1 RAs) and dual glucose-dependent insulinotropic polypeptide (GIP)/GLP-1 RAs for the management of weight loss—through telehealth platforms and direct distribution. In doing so, DTC models reduce reliance on traditional intermediaries such as in-person clinical visits, retail pharmacies, and insurance companies. This white paper highlights the impact of the DTC pharmaceutical care model on patient care.

Background

Growth in advertising from the 1980s into the 2000s drove the evolution of DTC care models, with drug manufacturers targeting patients directly.[1] Advertising directly to consumers became a key health communication strategy, driving greater patient awareness, self advocacy, and increased engagement with healthcare providers.[2] Today, integrated digital platforms go beyond advertising to provide medication fulfillment to patients.

Typical features of DTC care models include virtual intake and prescribing conducted through online questionnaires or brief visits with prescribers. Patient care may be supplemented with services such as educational modules, automated reminders, lifestyle coaching, and nursing support. Many models also emphasize transparent cash-pay pricing and subscription options to improve access and affordability. Medication access is typically provided through direct fulfillment or retail pickup.[3,4]

GLP-1 RAs and GIP/GLP-1 RAs have traditionally been obtained through a non-integrated pharmacy-dispensed care model where medications are filled at pharmacies not affiliated with or embedded within a health system, such as retail, specialty, or mail order pharmacies. In this model, clinicians evaluate patients in-person or virtually, prescribe therapy, and rely on these external pharmacies to dispense the medication. Insurance involvement is typically required to determine coverage. This non-integrated process often leads to fragmented care across prescribers, pharmacies, and payers, with limited longitudinal follow up or proactive adherence support. For GLP-1 RAs and GIP/GLP-1 RAs specifically, this model has been associated with delayed treatment initiation, high out-of-pocket (OOP) costs, and low adherence and persistence.[12–14]

THE IMPACT OF DTC ADVERTISING:[2]

- A key health communication strategy
- Drives greater patient awareness
- Inspires self advocacy
- Increases engagement with healthcare providers

For GLP-1 RAs and GIP/GLP-1 RAs specifically, a traditional access model has been associated with delayed treatment initiation, high out-of-pocket costs, and low adherence and persistence.[12–14]

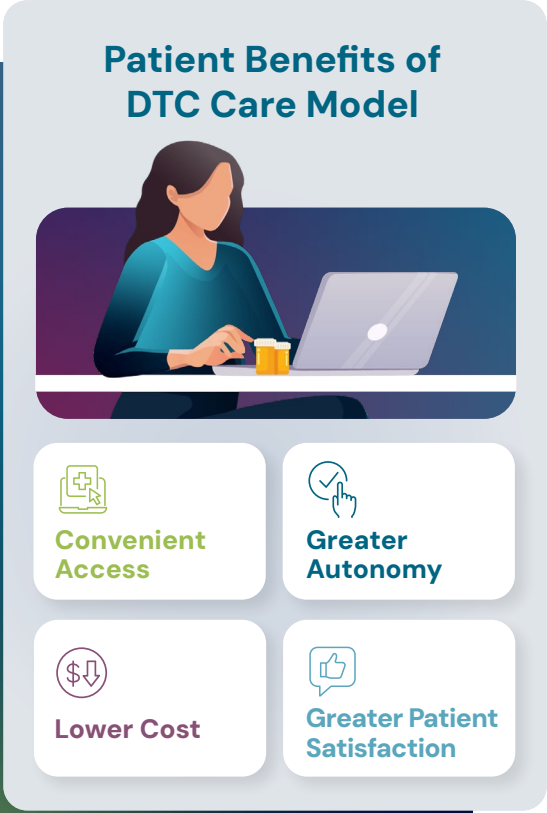
Benefits of the DTC Model

Many DTC programs are affiliated with telehealth companies which offer easy access to prescribers followed by quick delivery of medications. Telehealth utilization remains above pre-pandemic baselines and clinician surveys cite both improved access and high patient satisfaction when virtual options are available.[6,7,8] Additionally, the DTC model increases drug price transparency and allows consumers to purchase prescription medications at lower costs, often without insurance.

Currently, GLP-1 RA and GIP/GLP-1 RA drugs for weight loss dominate the DTC landscape. Supply shortages and insurance coverage barriers opened the market for pharmaceutical and third-party companies to offer these drugs directly to patients through their own digital platforms. For example, the manufacturer of tirzepatide offers a vial formulation of the weight loss medication Zepbound exclusively through their own pharmacy or Walmart pharmacies, solely on a self-pay basis.[9] These platforms are especially appealing to patients facing weight stigma or logistical barriers to in-person care or medication procurement.

Recent real-world data further support the effectiveness of these digital platforms. A retrospective cohort study of 655 patients treated with semaglutide through a nationwide telehealth platform demonstrated a mean weight reduction of 16.6% over 68 weeks. Safety outcomes were comparable to those observed in clinical trials, highlighting telehealth's potential as an effective and scalable approach to obesity management.[11]

Another retrospective cohort study evaluated treatment success, adherence, and adverse events among patients receiving liraglutide for weight loss through a DTC platform. After 50 days, adherence was high, with 94.1% of patients following the prescribed regimen. Adverse events occurred in 39.8% of patients and were most commonly gastrointestinal in nature; however, treatment persistence remained strong, with 86.4% of patients reporting a desire to continue therapy despite these effects.[10]



By contrast, real world adherence and persistence to GLP-1 RA and GIP/GLP-1 RA therapies are substantially lower in traditional pharmacy dispensed care models. Large U.S. claims based analyses of retail pharmacy dispensing indicate that only 27%–32% of patients remain adherent at one year when adherence is defined as a proportion of days covered (PDC) of at least 80%.[12] Long-term persistence declines further over time. In a three-year commercial claims analysis, only 8.1% of patients persisted with GLP-1 RA obesity therapy, with an average PDC of 37.5%.[13] Early discontinuation is common, with nearly one-third of patients stopping therapy within the first month, often before reaching a therapeutic dose.[14] These patterns have been attributed to cost barriers, adverse effects, limited follow-up, insurance interruptions, and fragmented care across prescribers and pharmacies.

Compared with traditional pharmacy dispensed care, DTC models demonstrate higher adherence to GLP-1 RA and GIP/GLP-1 RA therapies. However, longer term comparative studies are needed to determine whether these differences are sustained and translate into durable clinical benefit.

Risks and Limitations of the DTC Model

While the DTC model increases access and autonomy, concerns about patient safety persist as its rapid expansion, driven by shortages and rising demand, has fueled growth in compounded GLP-1 RA and GIP/GLP-1 RA production. The FDA recommends against the use of compounded medications because of the uncertainty regarding the final product's chemical composition, potency, and safety.[15] Unlike FDA-approved products, compounded formulations are not subject to FDA review for quality, safety, or efficacy. Some DTC platforms promote compounded versions of widely used medications, sometimes in delivery formulations like tablets or adding ingredients that do not exist in the FDA-approved product.[17]

A pharmacovigilance review analyzed 81,078 reports of compounded GLP-1 RA medication products from the FDA's Adverse Event Reporting System (FAERS) between 2018 to 2024. This review found higher rates of nausea, abdominal pain, diarrhea, cholecystitis, and hospitalizations among patients on compounded formulations of GLP-1 RA products compared to non-compounded formulations.[18] The FDA released an alert regarding the dangers of compounded semaglutide. Errors such as incorrect syringe sizes, miscalculated doses by clinicians, and incorrect patient administration have led to semaglutide overdoses associated with severe GI symptoms, dehydration, and emergency room visits.[17]

Although DTC programs may reduce barriers to therapy initiation, they often lack comprehensive medical evaluation, ongoing safety monitoring due to limited access to full medical records, and effective communication among multidisciplinary team members.[20] A poll by KFF Health News found that among adults who had taken a GLP-1 RA drug for weight loss, 76% of respondents received a prescription from their primary care doctor or specialist, while 17% obtained the medication from an online provider or website and 9% from a medical spa or aesthetic center, highlighting the various pathways to acquire medication.[16] An informed consent process that ensures full comprehension of their medical treatment, available alternatives, and potential harms before agreeing to treatment is essential for optimal patient outcomes. DTC platforms rarely provide clinical evaluation, patient education, and coordination with existing care teams.[5]

As DTC models grow, patient safety must become a top priority. Compounded GLP-1 RA and GIP/GLP-1 RA products lack the regulatory oversight needed to ensure consistent quality, potency, and sterility. Without FDA review, patients face heightened risks of dosing errors and contamination, thus leading to preventable adverse effects. Stronger regulatory standards and transparent, comprehensive education within DTC platforms are essential to protecting patients.

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A pharmacovigilance review of 81,078 reports found **higher adverse event rates with compounded formulations of GLP-1 RA products** compared to non-compounded formulations, including:[18]

- **Nausea**
- **Abdominal pain**
- **Diarrhea**
- **Cholecystitis**
- **Hospitalizations**

Patients who have taken a GLP-1 RA drug for weight loss:[18]

76%	received a prescription from a primary care doctor or specialist
17%	obtained the medication from an online provider or website
9%	received it from a medical spa or aesthetic center

Comparative Model: Shields Health Solutions

Shields Shields Health Solutions employs a bespoke, integrated specialty pharmacy care model to provide coordinated care and improve medication access for patients with chronic conditions. This model utilizes nationally certified pharmacy technicians as clinic-facing liaisons to promptly complete prior authorizations, obtain financial assistance, and proactively schedule refills. Clinical pharmacists provide comprehensive drug therapy education and ongoing management to enrolled patients at partnered healthcare systems. Patients have unlimited access to clinical guidance, ensuring timely interventions for adverse events and adherence challenges. Clinical pharmacists also provide non-medication support to patients to help achieve their goals including screening and referrals for social determinants of health (SDOH) and individualized coaching regarding diet, exercise and other healthy life modifications.

Despite well-documented challenges related to cost and tolerability that limit adherence to GLP-1 RA and GIP/GLP-1 RA therapies, patients supported through the Shields Health Solutions care model demonstrate high adherence and substantially lower OOP costs. A recent white paper reported that patients in the Shields Health Solutions model achieved a mean PDC of 93%, comparable to adherence rates reported in DTC models (~94%) and higher than observed rates in the traditional care model (27–32%).[10,13,20] The average monthly copayment for patients filling through the Shields Health Solutions model is $71. By comparison, published analyses of the traditional pharmacy model commonly cite an average patient OOP cost of approximately $300–$500 per month, reflecting insured patients with partial coverage. Reported OOP costs in the traditional model range from $900–$1,400 per month for uninsured patients and $25–$600 per month for insured patients, depending on benefit design and use of cost assistance programs.[21,22] DTC pricing varies by platform, with average OOP costs for cash-paying patients typically ranging from $250–$350 per month.[23,24] Collectively, these findings highlight Shields Health Solutions' effectiveness in reducing financial barriers and promoting sustained adherence to therapy.

Average Monthly OOP Cost of GLP-1 RA and GIP/GLP-1 RA Weight Loss Therapies

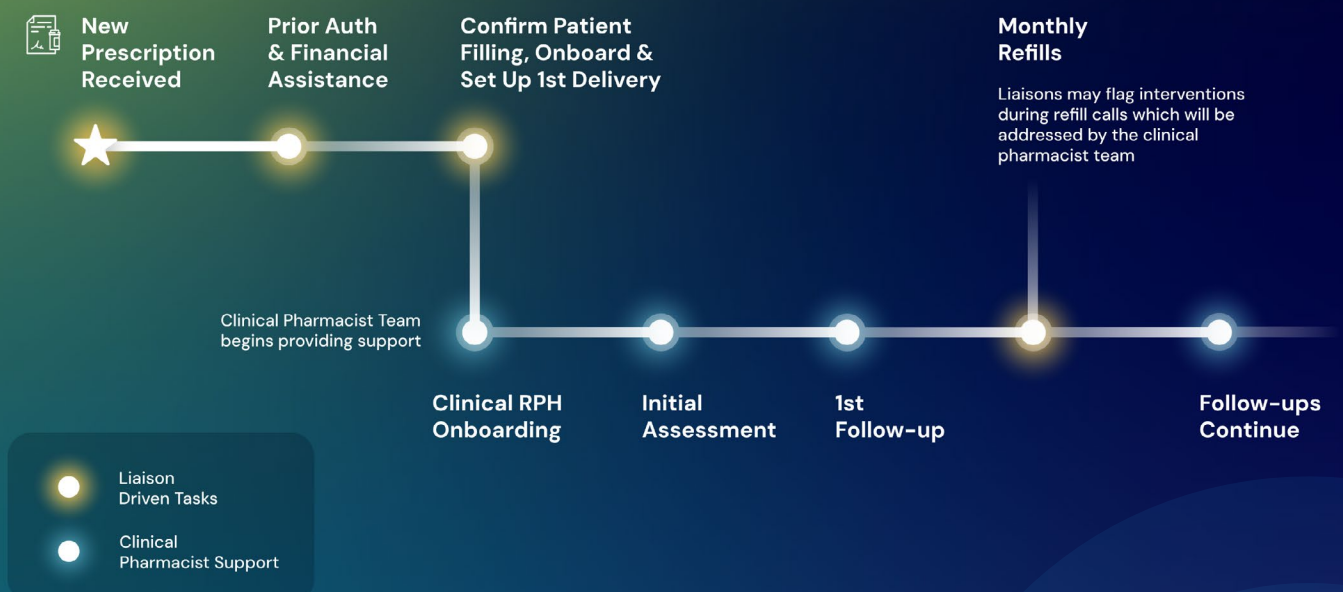
Care Model	Average Monthly OOP Cost ($)
Shields Health Solutions Model	$71*
Traditional Care Model	$300–$500*
DTC Care Models	$250–$350**

* Includes costs without insurance and with insurance +/- cost savings programs

** Cash-pay rate

OOP = Out-of-Pocket

Shields Health Solutions Care Model



Conclusion

DTC care models represent an important shift in healthcare offering increased access, autonomy, and transparent pricing for patients. For GLP-1 RA and GIP/GLP-1 RA treatments, evidence suggests that these models may also improve short-term adherence. However, these benefits are diminished by notable risks related to patient safety, care fragmentation, and the growing use of compounded medications lacking FDA oversight. Limited clinical evaluation, inconsistent follow-up, and minimal coordination with established healthcare teams raise concerns about long-term outcomes, treatment persistence, and preventable adverse events.

Shields Health Solution's integrated care model improves upon many limitations of the DTC care models. Continuous pharmacist-led monitoring, robust financial assistance navigation, and seamless collaboration with prescribing clinicians contribute to durable treatment persistence and improved patient safety.

As GLP-1 RA and GIP/GLP-1 RA therapy demand increases, care models that integrate digital access with longitudinal clinical oversight will be essential to ensuring safe, effective, and sustainable patient outcomes.

Comparison of Traditional, Direct-To-Consumer, and Shields Health Solutions Integrated Care Models for GLP-1 RA and GIP/GLP-1 RA Therapies

Dimension	Subcategory	Traditional Model	DTC Models	Shields Health Solutions Model
Safety and Monitoring	Provider Follow Up	✓		✓
	Integrated Care			✓
	Pharmacist Led Monitoring			✓
Financial	Insurance Prior Authorization Support			✓
	Affordability Support		✓	✓
	Transparent Cash Pricing		✓	
Adherence	Fast Initiation		✓	✓
	Auto Refill	✓	✓	
	Adherence Check Ins			✓

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About Shields Health Solutions

Shields Health Solutions (Shields) is the premier specialty pharmacy accelerator in the country. The Shields Performance Platform, an integrated set of solutions, services and technology, is intentionally designed to elevate payer and drug access for specialty pharmacies, elevate health outcomes for complex patients, and elevate growth throughout the entire health system.

As the foremost experts in the health system specialty pharmacy industry, Shields has a proven track record of success including access to over 90 percent of all limited distribution drugs (LDDs) and most (health insurance) payers in the nation; and a clinical model proven to lower total cost of care by 13%. In partnership with more than 80 health systems across the country through national-scale collaboration, Shields has a vested interest in delivering measurable clinical and financial results for health systems.

To learn more visit Shieldsrx.com

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