The BALANCE Model, GLP-1 Coverage and the Peptide Regulatory Collision: What Every Health Tech Operator and Investor Needs to Know Right Now

APR 08, 2026

Abstract

CMS launched the BALANCE Model in December 2025, a 1115A Innovation Ce voluntary model that for the first time waives the Part D statutory exclusion on v loss drugs, negotiating net prices of $245/month for Zepbound and model drugs Novo Nordisk (Ozempic, Rybelsus, Wegovy) and Eli Lilly (Mounjaro, Zepbound, pending FDA approval, orforglipron)

The Part D application deadline is April 20, 2026, with an 80% beneficiary participation threshold that CMS will evaluate by April 30, 2026 to determine whether the model launches in Medicare in January 2027

A Medicare GLP-1 Bridge demonstration launches July 2026 at $50/month copay operating entirely outside the Part D benefit structure, meaning plans carry zero

Medicaid states can join on a rolling basis from May 2026 through January 2027, executing supplemental rebate agreements that reflect CMS-negotiated key term

Simultaneously, FDA peptide regulation is in upheaval: semaglutide and tirzepat were removed from the drug shortage list in early 2025, HHS Secretary Kennedy announced in February 2026 that ~14 of 19 restricted Category 2 peptides would return to Category 1 compounding status, and the formal reclassification public remains pending

The convergence of BALANCE's government-negotiated GLP-1 pricing with FD peptide compounding crackdown and subsequent partial reversal creates a comp opportunity map for providers, pharmacies, manufacturers, wellness companies, telehealth, payers, entrepreneurs, and investors

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What BALANCE Actually Is (and What It Isnt)

The BALANCE Model (Better Approaches to Lifestyle and Nutrition for Comprehensive hEalth, because government acronyms gonna government acron a CMMI 1115A demonstration. That statutory authority matters. It means CMS waive provisions of the Social Security Act to test payment and delivery models. this case the single most consequential waiver is of Section 1860D-2(e), which ha historically excluded drugs used for weight loss from Part D coverage. That excl has been the law since 2003. Twenty-plus years of Part D and weight loss drugs never been covered. BALANCE changes that for participating plans.

But it is voluntary. Manufacturers, states, and Part D sponsors all opt in. The m runs January 2027 through December 2031 for Part D, with Medicaid states join a rolling window from May 2026 through January 2027. CMS negotiated directly Eli Lilly and Novo Nordisk during a pre-implementation period from January 12 through February 5, 2026, and those manufacturers executed Participation Agreements by February 28, 2026. The negotiated drugs include all formulation Mounjaro, Ozempic, Rybelsus, and Wegovy, the KwikPen formulation of Zepbou and orforglipron tablets if FDA approves them. The net price for Zepbound is $ per month supply. Novo's pricing for its portfolio is listed in the RFA appendix follows similar negotiated terms.

What BALANCE is not: it is not a permanent statutory change. It is not the IRA Medicare Drug Price Negotiation Program, although it interacts with it in weir (more on that below). It is not a guarantee of coverage for any individual patient. it absolutely is not universal, because if fewer than 80% of Part D beneficiaries a enrolled in participating plans, the whole Medicare side does not launch.

The Mechanics: Pricing, Rebates, and t Facilitated DIR Field

The payment plumbing here is genuinely interesting and worth understanding because it tells you where the money flows. CMS negotiated a net price with manufacturers. That net price includes all discounts, rebates, and price concessi For drugs that are also selected under the IRA's Negotiation Program (which ap

to some of these products), CMS is waiving the Maximum Fair Price requiremen Instead, plans will use WAC as the base for gross drug cost calculations, and manufacturers will pay rebates through a new PDE field called Facilitated DIR (

The FAD field calculates the difference between the ingredient cost the plan rep on the PDE and the sum of the GLP-1 Discounted Price plus the Manufacturer Discount Program amount. Manufacturers get invoiced quarterly through the ex MDP portal with separate model-specific invoices. Plans do not report the FAD amount on the DIR Report for Payment Reconciliation, but CMS incorporates it annual reconciliation.

Why does this matter? Because it means plans are not chasing manufacturers fo rebates. CMS is intermediating the rebate flow, which dramatically reduces administrative friction for plans. It also means CMS has real-time visibility into whether plans are complying with price guidance, and it protects beneficiary an physician data by keeping the invoicing process clean on the CMS side rather th requiring plans to share utilization data directly with manufacturers.

There is a 340B adjustment baked in too. Rebates get reduced by up to 5% to acc for the fact that manufacturers will be paying model rebates on units purchased 340B covered entities at already-discounted prices. This is a small but importan detail for health systems running 340B programs who are evaluating the model.

Part D Plan Sponsors: The 80% Thresh Problem

This is the single most important near-term question in the entire model. CMS requires that plans representing at least 80% of NAMBA-eligible beneficiaries ap to participate. If they do not hit that number, BALANCE does not launch in Me in 2027. Period. CMS calculates the threshold based on February 2026 enrollme data, projected forward. The denominator includes all NAMBA-eligible plan typ plus Defined Standard plans (even though DS plans cannot actually participate). numerator is beneficiaries in plans that applied. SNPs and EGWPs are excluded the calculation even though they can participate.

The application deadline was April 20, 2026. CMS targets April 30, 2026 to noti plans whether the threshold was met. As of this writing, that notification should imminent or already out. If it cleared, the next milestone is June 1, 2026, when p indicate participation in HPMS and submit bids reflecting BALANCE. Contract addendums execute in September 2026.

Participation is at the parent organization level, which is a big deal. A parent or include all of its Enhanced Alternative plans. It must also include 90% of benefi enrollment in its basic plans (excluding ineligible types and DS plans). DS plans cannot participate because they cannot offer the reduced cost sharing while maintaining DS status, but parent orgs can convert DS plans to BA or AE benefi types for 2027. EGWPs can participate but are not required to.

For plans, the decision tree is: if enough of the market applies, you are probably to have to participate because not participating means your competitors offer $5 $125 copay GLP-1s and you do not. The adverse selection concern is real (people want GLP-1s will shop for plans that cover them) and that is exactly why CMS s 80% threshold so high. If basically everyone is in, adverse selection washes out.

Medicaid: The Rolling On-Ramp

The Medicaid side works differently. States apply through a Qualtrics link by Ju 2026, execute State Agreements with CMS by January 1, 2027, and enter supplen rebate agreements with each participating manufacturer. States that need SPAs state legislation can work with CMCS to get those in place. States can start as ea May 2026 with just FFS populations and bring managed care populations in late long as everything is live by January 1, 2027.

The coverage criteria are identical to the Part D criteria (same BMI thresholds, s comorbidity requirements), and the Medicaid Key Terms are standardized. State vary terms with CMS approval but cannot disadvantage one model drug relative another. Managed care plans within participating states must apply the same ac policy as FFS.

For investors watching the Medicaid managed care space, this matters because M in participating states will need to cover these drugs at negotiated prices with standardized PA criteria. That is new cost exposure but also new opportunity if drugs reduce downstream utilization of hospitalizations, ER visits, and specialty The question of whether GLP-1s are net savings or net cost for Medicaid popula is going to be the subject of the model evaluation, but anyone who has been follo the cardiovascular outcomes data from SELECT and STEP-HFpEF trials knows clinical signal is strong.

The Bridge Demo: Why July 2026 Matte More Than January 2027

Before BALANCE even launches, CMS is running a separate Medicare GLP-1 payment demonstration starting July 2026. This is often overlooked but it is argu the bigger near-term catalyst. The bridge demo operates entirely outside the Par benefit's coverage and payment flow. Part D sponsors carry zero risk. CMS uses a single central processor to manage prior authorization, claims adjudication, and payment to pharmacies. Eligible beneficiaries pay $50 per month for Wegovy or Zepbound.

This means that starting mid-2026, millions of Medicare Part D beneficiaries ca access GLP-1s for weight management at $50/month regardless of what their pla does. The catch: it ends December 31, 2026. So beneficiaries who start on the bri need to enroll in a BALANCE-participating plan for 2027 to maintain access. CM has said they will do beneficiary outreach and education around this transition.

From a market dynamics perspective, the bridge demo is going to create a massiv cohort of Medicare patients on GLP-1s before BALANCE launches. That is dem that gets locked in. Plans that do not participate in BALANCE will lose those members during open enrollment. This is the stick that makes the 80% threshol achievable.

Provider Strategy: PA Criteria, Auto-Lookback, and Patient Volume

The prior authorization criteria under BALANCE are more generous than many expected. The three tiers are: (1) BMI 35 or above with lifestyle modification, (2) 30 or above with specific comorbidities like HFpEF, uncontrolled hypertension, stage 3a+, moderate/severe OSA, or noncirrhotic MASH F2-F3, and (3) BMI 27 o above with pre-diabetes, previous MI, previous stroke, or symptomatic PAD. Pat with type 2 diabetes, MASH with F2-F3 fibrosis, or OSA do not even need to me BMI threshold for the lifestyle modification pathway.

The Auto-Lookback provision is really interesting for health IT companies. Plan directed to try to confirm PA through automated review of patient health record ICD-10 code matching before requiring provider attestation. If the automated cl fails, then provider attestation is sufficient. This creates an opportunity for com building prior authorization automation, clinical data matching, and interoperal tooling. The plans that execute Auto-Lookback well will have lower administrati costs and faster patient access.

For provider organizations, the volume implications are significant. CMS is esse telling every primary care doc in America that their Medicare patients with BMI and common comorbidities can now get GLP-1s covered. The prescribing volum going to be enormous. Practices need to think about PA workflow capacity, patie education at scale, and monitoring protocols. Obesity medicine as a specialty is a to see a massive demand surge.

Pharmacy and PBM Implications

Participating plans must reimburse in-network pharmacies at no less than WAC sales tax plus a dispensing fee. That WAC-plus floor is a real win for pharmacies were worried about being squeezed. Mail order and specialty pharmacy are both eligible channels. The cost sharing maximums ($50 for EA/EGWP plans, $125 fo

AE/BA plans) apply at all in-network pharmacy types, preferred and non-preferr retail and mail.

For PBMs, the FAD field changes rebate economics. PBMs typically negotiate ar retain a share of DIR rebates. Under BALANCE, the manufacturer rebates flow through CMS's invoicing system, not through PBM-negotiated contracts. PBMs need to figure out how model drugs interact with their existing rebate structure non-model indications and non-model plans. This is a structural change to the P value proposition for this drug class.

Community pharmacies should be paying close attention to the bridge demo's ce processor model. If CMS builds an effective centralized claims processing syster the bridge, that infrastructure could influence future payment models beyond G 1s.

Pharma Manufacturers: Lilly and Novo a Negotiated Cage

Eli Lilly and Novo Nordisk both signed Participation Agreements. They accepte $245/month net pricing (for Zepbound at least, and comparable pricing for Novo products). That is roughly 75-80% off WAC depending on the specific product. I exchange they get access to the entire Medicare and Medicaid population at negotiated volume with standardized coverage criteria.

The manufacturers are also required to fund lifestyle support programs at no co plans or beneficiaries. These programs must cover diet and nutrition counseling physical activity support, medication adherence tools, and must be delivered on recurring basis with accessibility accommodations for patients with limited digi access. The safe harbor at 42 CFR 1001.952(ii) protects manufacturers from anti kickback exposure on these programs, but only within the model.

For Lilly specifically, orforglipron is the sleeper hit. If FDA approves the oral GIP/GLP-1 receptor agonist, it enters the model immediately. An oral formulati $245/month with Medicare and Medicaid coverage would be enormously disrupt

the injectable-dominated market. Lilly filed the NDCs in the RFA appendix, whi suggests they are confident on approval timing.

Wellness Companies and Lifestyle Support: The Mandated Wraparound

The lifestyle support mandate is where wellness, digital health, and coaching companies should be paying very close attention. Manufacturers are on the hook provide these programs, but the RFA language around program requirements re like a digital health company's product spec sheet: diet and nutrition with GI sic effect management, physical activity promotion, medication adherence with rem and injection site guidance, recurrent engagement with weight logging and goal review, and scalable delivery including offline options for patients without digit access.

Lilly and Novo are going to need partners to deliver this at the scale of the Medi and Medicaid population. They are not going to build this in-house. That means contracts for digital health platforms, health coaching companies, nutrition counseling services, and patient engagement technology. If you are building in tl GLP-1 support ecosystem (think Noom, Calibrate-style models, clinical coachin platforms, remote patient monitoring for metabolic health), the manufacturer lit support mandate just created a guaranteed buyer.

CMS has also said it expects to revisit lifestyle support requirements annually ar may shift responsibility to states and MA-PD plans in future years. That is a sign that this could evolve from a manufacturer-funded mandate to a plan-funded be which would further expand the addressable market for wellness and coaching companies.

D2C Telehealth: The Compounding Cliff Meets Government Pricing

This is where things get really spicy. The d2c telehealth GLP-1 market has been on two pillars: compounded semaglutide at $200-400/month, and the ability to prescribe without the friction of traditional insurance PA. BALANCE and the F regulatory actions are attacking both pillars simultaneously.

On the compounding side, FDA removed semaglutide from the drug shortage lis February 2025 and tirzepatide in October 2024. The legal basis for shortage-bas 503B compounding effectively evaporated, though ongoing litigation and 503A patient-specific compounding have kept some supply flowing. As of April 2026, landscape is messy: 503A compounding continues under physician prescription, 503B facilities are operating under court injunctions or enforcement uncertainty the gray market is still active.

Meanwhile, BALANCE introduces branded GLP-1s at $50/month copay for Med EA/EGWP plans and through the bridge demo. Even the $125/month AE/BA cop competitive with compounded pricing. For Medicaid populations, cost sharing w even lower. This fundamentally changes the value proposition for d2c telehealth companies selling compounded GLP-1s to commercially insured or cash-pay pat because the comparison anchor just dropped from $1,000+/month brand name to 245/month government-negotiated.

Companies like Hims and Hers, Ro, and the dozens of smaller d2c GLP-1 telehe plays need to be thinking about what their business looks like when the governn offering branded Wegovy at $50/month. The cash-pay compounded model only w if it is cheaper or more accessible than the covered option. For Medicare and Medicaid patients, that calculus just shifted dramatically. For commercially insu patients, the BALANCE pricing will create employer and plan pressure to match

FDA Peptide Activity: The Category 2 t Category 1 Reversal

Running in parallel with BALANCE is a wild chapter in FDA peptide regulation September 2023, FDA placed 19 commonly used peptides on the Category 2 rest list, effectively banning compounding pharmacies from preparing them. This in

BPC-157, Thymosin Alpha-1, TB-500, CJC-1295/Ipamorelin, AOD-9604, and oth widely used in wellness and longevity medicine.

Then in February 2026, HHS Secretary Kennedy announced on the Joe Rogan po (yes, really) that approximately 14 of the 19 would be reclassified back to Catego restoring legal compounding access under physician prescription. The five expec stay restricted include Melanotan II, GHRP-2, GHRP-6, LL-37, and PEG-MGF. early April 2026, the formal FDA publication has not been released, so compoun pharmacies technically cannot resume production yet.

The connection to BALANCE is not immediately obvious but it matters for understanding the broader regulatory picture around peptide therapeutics in government health programs. GLP-1 receptor agonists like semaglutide and tirzepatide are themselves peptides. They are fully FDA-approved peptide drugs compounding crackdown on GLP-1s (shortage list removal, enforcement actions against compounders, Lilly and Novo litigation against clinics) and the partial re on non-GLP-1 peptides reflect two different regulatory postures for two differer categories of peptide products.

For the investment thesis, the regulatory bifurcation creates distinct lanes. FDA approved GLP-1 peptides are moving toward government-negotiated pricing and broad coverage through BALANCE. Non-approved peptides used in wellness an longevity are moving toward restored compounding access under physician supervision, but without insurance coverage and with ongoing quality concerns. are fundamentally different market structures and business models, and conflati them is a mistake a lot of generalist investors make.

Payer Strategy: Risk Corridors, Advers Selection, and Bid Uncertainty

The risk corridor modification is a clever incentive that deserves more attention Under standard Part D, the first risk corridor threshold is plus or minus 5% of th target amount, with plans bearing 100% of the variance within that band. BALA offers an optional narrowed first threshold of plus or minus 2.5% for plans that c

and subsequently experience model drug utilization more than one standard dev above the mean for their plan type.

The mechanics are retrospective: CMS calculates utilization rates after the plan compares them to the mean and standard deviation across all eligible participati plans of the same type, and narrows the corridor for plans that got hit hardest. T essentially CMS saying "if you get adverse selection, we will share the risk." It is available for the first two years of the model, with potential extension based on results.

For payer actuaries, the bid uncertainty is the real challenge. Plans need to subn 2027 bids in June 2026 reflecting BALANCE participation. They are pricing a ne drug class that has never been in the Part D benefit. They do not know what utilization will look like. They do not know how many of their members will me PA criteria. The narrowed risk corridor helps, but the first year is going to be a massive exercise in actuarial estimation with limited data. Plans with better anal capabilities, especially those that can model the intersection of their current membership demographics, chronic condition prevalence, and the specific PA cr will have a meaningful advantage in bid accuracy.

The Entrepreneur and Investor Lens

So where does all of this leave entrepreneurs building companies and investors deploying capital in health tech?

First, the obvious: anything that reduces friction in the GLP-1 prescribing and monitoring workflow for participating plans and providers is going to see dema automation that can handle the BALANCE-specific criteria and auto-lookback I 10 matching. Clinical decision support that helps PCPs identify eligible patients their panel. Remote monitoring and coaching platforms that can serve the lifesty support mandate. Lab ordering and metabolic health monitoring tooling. All of are immediate build opportunities.

Second, the less obvious: BALANCE creates a data exhaust that will be extremel valuable. CMS is going to collect PDE data, utilization data, clinical outcomes d and patient-reported measures across the entire model population over five year Companies that position to help CMS, plans, states, or manufacturers analyze th data, reconcile rebates, monitor quality metrics, or support evaluation activities find willing buyers. The FAD field alone creates a new data infrastructure requirement for every participating plan.

Third, the competitive dynamics in d2c telehealth are about to shift hard. Comp built on compounded GLP-1 margin are going to need to pivot toward branded access facilitation, comprehensive metabolic health management, or differentiat clinical services that justify their existence in a world where Medicare patients c Wegovy for $50. The companies that survive this transition will be the ones that always more than a pharmacy arbitrage play.

Fourth, the wellness and lifestyle support space just got a government-mandated expansion. Manufacturers need to procure these services at scale. Plans may nee procure them in future model years. The specification in the RFA (diet/nutrition physical activity, medication adherence, recurrence, scale/accessibility) reads lik product requirements doc. Companies that can deliver evidence-based lifestyle interventions at Medicare-and-Medicaid scale, including offline delivery for dig underserved populations, have a clear path to contracted revenue.

Fifth, and this is the longer-term play, watch what happens with orforglipron. If gets FDA approval for an oral GLP-1 that enters the model at $245/month, the e delivery model changes. No more cold chain. No more injection training. No mo specialty pharmacy gatekeeping. Oral administration at government-negotiated is a completely different product from injectable semaglutide at $1,300/month. T downstream effects on patient adherence, prescriber behavior, pharmacy logistic competitive positioning are going to be massive.

On the peptide side, the Category 2 to Category 1 reversal creates a separate but parallel opportunity in wellness and longevity medicine. BPC-157, Thymosin Al and the other returning peptides will flow through compounding pharmacies un

physician prescription, serving a cash-pay, wellness-oriented population that is l distinct from the BALANCE population. Companies building peptide therapy platforms, compounding pharmacy networks, or clinical protocols for non-GLP- peptides should be scaling their physician networks and pharmacy relationships ahead of the formal FDA reclassification publication.

The macro picture is that the federal government just decided to become the sin largest purchaser of GLP-1s in the world, at prices 75-80% below list, with manc lifestyle support and standardized coverage criteria, across both Medicare and Medicaid. At the same time, FDA is unwinding its most aggressive compounding restrictions on non-GLP-1 peptides while maintaining pressure on compounded 1s. These two regulatory vectors create very different market structures for very different patient populations, and the companies and investors that understand distinction clearly will be positioned to capture the most value. The ones who tr "peptides" as a monolithic category or who assume the compounding arbitrage window stays open forever are going to get caught.

The next 90 days are going to tell the story. The 80% participation threshold dec The bridge demo operational guidance. The FDA formal peptide reclassification publication. State Medicaid applications rolling in. Any one of these could resha assumptions. Keep close to the primary source documents, read the RFAs yourse and do not rely on secondary coverage that smooths over the details. The details where the alpha is.

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