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March 2026 Edition

In March: all 15 IRA Cycle 3 manufacturers confirmed participation including the first-ever Part B drugs, the FDA approved three landmark therapies, Virginia enacted MFN-based drug pricing, and MedPAC documented the full IRA Part D redesign impact on plan bids.

Each item below is a compressed briefing on one policy development: what changed and what it means for your team right now. No filler. No 30,000-foot commentary. If it is in here, it has a direct line to formulary position, reimbursement rates, or patient volume.

IN THIS EDITION

FEDERAL

DRUG PRICING & NEGOTIATION

IRA Cycle 3: All 15 Manufacturers Confirm Participation (March 13)

First-ever inclusion of Part B physician-administered drugs; active negotiations begin

Update: CMS announced on March 13, 2026 that all 15 manufacturers of drugs selected for the third IRA negotiation cycle (IPAY 2028) have signed agreements to participate, including the one manufacturer selected for renegotiation. This is the first cycle to include drugs payable under Medicare Part B, covering oncology and specialty physician-administered infusions for the first time. Manufacturer data submissions were due March 1; active negotiation workflows are now underway. MFPs are due November 30, 2026, with prices effective January 1, 2028.

Industry Impact: Universal participation removes any remaining ambiguity -- all 15 manufacturers are now actively engaged in negotiations that will govern pricing through at least 2028. For oncology and specialty infusion manufacturers, this is the first federal negotiation cycle that directly affects Part B reimbursement. HOPDs, oncology practices, and physician-administered drug manufacturers must begin IPAY 2028 portfolio exposure modeling immediately.

GENEROUS Model Deadline Extended to April 30 (March 2)

CMS extends Medicaid MFN pricing model application window; small/mid-size manufacturer meetings begin April 1

Update: CMS announced on March 2, 2026 an extension of the GENEROUS (GENErating cost Reductions fOr U.S. Medicaid) Model manufacturer application deadline from March 31 to April 30, 2026. The GENEROUS Model allows participating state Medicaid programs to purchase selected drugs at prices aligned with international benchmarks. CMS cited manufacturer feedback and specifically noted its goal of enabling small and mid-size manufacturers to participate. CMS will begin meetings with interested manufacturers on April 1, 2026 and plans a town hall in Spring 2026. The final participation deadline remains June 30, 2026.

Industry Impact: The GENEROUS Model creates new best price and supplemental rebate implications across entire manufacturer portfolios. Medicaid net prices aligned with international benchmarks could compress existing supplemental rebate arrangements and force manufacturers to reassess their Medicaid access strategy. Manufacturers of any size with Medicaid-covered products should evaluate GENEROUS participation or non-participation before the June 30 final deadline.

Medicare GLP-1 Bridge FAQs Released (March 3)

CMS publishes operational details: $50 copay, centralized PA processor, BMI eligibility confirmed

Update: CMS released operational FAQs for the Medicare GLP-1 Bridge on March 3, 2026, confirming the $50/month flat copay, coverage of Wegovy and Zepbound (Foundayo was not yet approved at this point), a centralized prior authorization processor operating outside the standard Part D benefit, and BMI-plus-comorbidity eligibility criteria. Part D plans bear no financial risk for the Bridge program. Additional guidance on PA appeals was signaled for Spring 2026.

Industry Impact: The FAQ release gave market access teams their first concrete operational picture of the Bridge. The centralized PA processor model -- operating entirely outside Part D -- creates novel implications for manufacturer rebate strategy, patient support programs, and specialty pharmacy channel planning. Plans bear no risk, but manufacturers negotiated the $245/month net price directly with CMS.

BALANCE Model Applications Open (March 9)

CMS completes Lilly/Novo Nordisk pricing negotiations; state Medicaid and Part D applications open

Update: CMS completed pricing negotiations with Eli Lilly and Novo Nordisk and opened BALANCE Model applications to state Medicaid agencies and Part D plan sponsors on March 9, 2026. The Medicaid component was targeted to launch as early as May 2026; the Part D component was targeted for January 2027. States and Part D plan sponsors received the request for applications and began evaluating participation.

Industry Impact: The BALANCE Model creates a separate negotiated access track for GLP-1s in Medicaid distinct from existing supplemental rebate agreements. State participation will be uneven, creating a fragmented Medicaid access map for obesity drugs. Manufacturers must assess whether BALANCE terms are more favorable than existing state SRAs and model the formulary and access implications of state-by-state participation decisions.

MFN Congressional Scrutiny Escalates (March 5)

Bipartisan leaders demand unredacted MFN agreements; March 23 manufacturer response deadline

Update: Bipartisan House and Senate leaders formally demanded unredacted Most Favored Nation pricing agreements from the Trump administration in early March 2026, setting a March 23 deadline for manufacturer responses. Congressional intent to potentially codify MFN into statute -- extending MFN pricing beyond the current executive-action framework -- represents a long-term commercial pricing exposure for branded manufacturers.

Industry Impact: If MFN pricing is codified into law, the commercial pricing exposure extends well beyond Medicaid and affects the entire portfolio of manufacturers with international price differentials. Manufacturers should monitor the congressional response to the unredacted agreement disclosures and assess their MFN exposure under various legislative scenarios.

MedPAC March Report: Part D Bids Up 33% in 2026; IRA Redesign Impact Documented

National average Part D bid increased 33% in 2026 following 180% surge in 2025; reinsurance shift flagged

Update: MedPAC's March 2026 Report to Congress documented that the national average monthly bid amount (NAMBA) for Part D plans increased 33% in 2026 to $239 per member per month, following a 180% increase in 2025. MedPAC attributed the surge to the IRA's shift from cost-based federal reinsurance to capitated monthly payments, elimination of cost sharing above the OOP threshold, and utilization uncertainty created by the redesign. Total expected basic benefit costs increased 35% in 2026.

Industry Impact: Surging plan bids directly translate to higher Medicare capitated payments and create significant uncertainty for plan financial modeling. For specialty drug manufacturers, the utilization uncertainty that drove bid increases signals that payers will intensify formulary management and utilization controls to manage projected spending against capitated payment levels in 2026 and beyond. Manufacturers should expect tighter PA criteria and formulary positioning pressure as plans seek to control costs under the new benefit structure.

FEDERAL

COVERAGE & PRIOR AUTHORIZATION

House Oversight Letter: Six Protected Classes and Step Therapy (March 19)

Chairmen Comer and Aderholt urge CMS to prevent step therapy from circumventing protected class protections

Update: House Oversight Committee Chairmen Comer and Aderholt formally wrote to CMS Administrator Oz on March 19, 2026, urging CMS to prevent benefit designs that use step therapy and prior authorization to circumvent Medicare Part D's six protected class protections: antineoplastics, antiretrovirals, immunosuppressants, antidepressants, antipsychotics, and anticonvulsants. The letter directly targeted PBM-driven formulary structures that effectively impose access barriers on drugs that are technically covered under protected class rules.

Industry Impact: The letter signals bipartisan congressional intent to scrutinize and potentially restrict step therapy and PA use in the six protected classes. For manufacturers of oncology, HIV, transplant, CNS, and seizure therapies, this creates a potential regulatory opening to challenge restrictive formulary designs. Market access teams should monitor CMS's response and assess whether their protected class products face step therapy or PA barriers in current MA and Part D plan designs.

FEDERAL

FDA APPROVALS

FDA Approves Icotyde (Icotrokinra): First Oral IL-23 Inhibitor for Psoriasis

J&J's first-in-class oral IL-23 receptor antagonist approved March 18 for moderate-to-severe plaque psoriasis

Update: The FDA approved Johnson & Johnson's Icotyde (icotrokinra) on March 18, 2026, the first and only targeted oral peptide that precisely blocks the IL-23 receptor, for the treatment of moderate-to-severe plaque psoriasis in adults and pediatric patients 12 years and older weighing at least 40 kg. Approval was based on the phase 3 ICONIC clinical development program. Head-to-head data demonstrated superiority versus deucravacitinib. Icotyde is indicated for patients who are candidates for systemic therapy or phototherapy.

Industry Impact: The first oral IL-23 inhibitor disrupts a formulary landscape dominated by injectable biologics and immediately creates step therapy sequencing, biologic tier displacement, and specialty rebate pressure across the immunology formulary. Payers must now decide whether to position Icotyde as a preferred first-line systemic or require biologic step therapy before oral

IL-23 access -- a decision with major implications for IL-17 and IL-23 biologic manufacturers currently holding preferred formulary status.

FDA Approves Awiqli (Insulin Icodec): First Once-Weekly Basal Insulin

Novo Nordisk's once-weekly basal insulin approved March 26 for type 2 diabetes; nationwide launch H2 2026

Update: The FDA approved Novo Nordisk's Awiqli (insulin icodec-abae) injection 700 units/mL on March 26, 2026, the first and only once-weekly long-acting basal insulin approved in the U.S. for adults with type 2 diabetes. Approval was based on the ONWARDS phase 3 program, which comprised four randomized trials in approximately 2,680 adults with uncontrolled type 2 diabetes demonstrating HbA1c reduction comparable to daily basal insulin. Awiqli reduces basal insulin injections from seven to one per week. Novo Nordisk expects a nationwide launch via the FlexTouch device in the second half of 2026.

Industry Impact: The first new class of basal insulin in over two decades disrupts daily insulin formulary placements, adherence assumptions, and long-term contracting relationships. Payers must now build formulary positioning, step therapy, and utilization management criteria for a once-weekly basal option that competes directly with established daily basal insulin franchise contracts. Manufacturers of daily basal insulins should assess their preferred formulary positioning vulnerability.

FDA Approves Lifyorli (Relacorilant) for Platinum-Resistant Ovarian Cancer

First selective glucocorticoid receptor antagonist approved March 25; combination with nab-paclitaxel; no biomarker required

Update: The FDA approved Corcept Therapeutics' Lifyorli (relacorilant) on March 25, 2026, in combination with nab-paclitaxel for adults with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received one to three prior systemic regimens including at least one bevacizumab-containing regimen. Lifyorli is the first FDA-approved selective glucocorticoid receptor antagonist (SGRA). Approval was based on the ROSELLA trial (n=381), which met dual primary endpoints of progression-free and overall survival improvement over nab-paclitaxel monotherapy. No biomarker selection is required.

Industry Impact: A biomarker-agnostic approval in platinum-resistant ovarian cancer creates a broad eligible population and immediate prior authorization criteria development requirements for HOPDs and oncology clinics. Payers must build combination therapy coverage criteria and assess budget impact against the existing second-line ovarian cancer landscape. The SGRA mechanism and oral dosing of relacorilant add novel clinical pathway considerations for payer medical policy.

FDA Approves Avlayah (Tividenofusp Alfa) for Hunter Syndrome Neurologic Manifestations

First new treatment for MPS II neurologic disease in nearly 20 years; accelerated approval March 25; blood-brain barrier penetration

Update: The FDA granted accelerated approval to Denali Therapeutics' Avlayah (tividenofusp alfa-eknm) on March 25, 2026, the first FDA-approved biologic designed to cross the blood-brain barrier for the treatment of neurologic manifestations of Hunter syndrome (MPS II) in pediatric and adult patients weighing at least 5 kg, initiated prior to advanced neurologic impairment. Approval was based on a Phase 1/2 trial (n=47) demonstrating 91% reduction in CSF heparan sulfate from baseline by week 24, with 93% of patients achieving normal-range levels. This is the first new treatment option for MPS II neurologic disease in nearly 20 years. Continued approval is contingent on confirmatory evidence from the Phase 2/3 COMPASS trial.

Industry Impact: Accelerated approval based on a biomarker surrogate endpoint in an ultra-rare disease raises coverage-with-evidence-development questions for payers building MPS II neurologic coverage criteria. Payers must build from scratch for a previously untreatable indication, including site-of-care criteria for intravenous infusion, confirmatory trial tracking requirements, and rare pediatric disease coding. The blood-brain barrier platform also sets a precedent for future CNS-targeted biologics entering the market.

Virginia Enacts MFN-Based Drug Pricing and PBM Accountability (March 30-31)

Affordable Medicine Act passes legislature March 30; S.B. 669 signed March 31; Ohio enacts parallel PBM reforms

Update: Virginia's legislature passed the Affordable Medicine Act (H.B. 483) on March 30, 2026, establishing a Prescription Drug Affordability Advisory Panel and adopting IRA Maximum Fair Prices for drugs purchased by Virginia-regulated health plans and state employee plans, effective January 1, 2027. On March 31, Governor Spanberger signed S.B. 669, mandating 100% rebate pass-through to carriers or patients at point of sale, requiring PBMs to offer fee-only compensation arrangements, and prohibiting a range of additional PBM practices. Ohio enacted parallel standalone PBM licensure and transparency reforms the same day.

Industry Impact: Virginia's adoption of IRA Maximum Fair Prices for state-regulated plans is a first-in-nation model that directly compresses manufacturer net revenue on covered products in that market. The 100% rebate pass-through mandate eliminates PBM spread pricing on the rebate side and creates immediate compliance obligations. Manufacturers with significant Virginia commercial or state employee plan volume should model the pricing impact. Ohio's simultaneous enactment signals a coordinated state-level PBM reform wave continuing through 2026.

OBBBA Medicaid Implementation: State Planning Accelerates

RAND models $664B in state Medicaid budget losses 2025-2034; KFF tracker updated; coverage loss modeling underway

Update: A RAND study published March 1, 2026 modeled $664 billion in state Medicaid budget losses from 2025 through 2034 under OBBBA provisions, with work requirements projected as the single largest driver. KFF's state implementation tracker was updated as states began accelerating coverage loss modeling across behavioral health, HIV, diabetes, and chronic disease portfolios. Nebraska was on track to be the first state to begin enforcement, with a May 1 enforcement date confirmed.

Industry Impact: Manufacturers with significant Medicaid-dependent patient populations in behavioral health, HIV, infectious disease, and chronic disease management must model state-by-state volume loss scenarios. The $664B in projected state budget losses will compress Medicaid reimbursement rates and accelerate managed care cost controls independent of enrollment loss. States facing the largest budget reductions -- Arizona, Iowa, Nevada, California, and New York -- represent the highest-priority modeling targets.

Federal PBM Reform Implementation: Consolidated Appropriations Act 2026

First full month of implementation planning for February 3 federal PBM reform package

Update: March 2026 was the first full month of implementation planning following enactment of the federal PBM reform package in the Consolidated Appropriations Act on February 3, 2026. Key provisions include any-willing-pharmacy requirements (effective 2028), semiannual rebate and spread pricing reporting mandates, and flat-fee compensation requirements for PBMs. PBMs and plan sponsors began compliance mapping, contract review, and operational planning across all affected business lines.

Industry Impact: The federal flat-fee compensation mandate and rebate transparency requirements fundamentally alter PBM incentive structures for formulary placement. Manufacturers that relied on rebate negotiations as the primary lever for preferred formulary position must reassess their contracting strategy as PBM compensation structures shift to fee-only models. The any-willing-pharmacy provision also creates new specialty pharmacy channel dynamics effective 2028.

Every item in this newsletter is a decision your team needs to make.

IRA Cycle 3 negotiations are active with Part B drugs in play for the first time. Virginia just adopted MFN pricing for state-regulated plans. Federal PBM reform is in implementation. None of this waits for your next quarterly review.

ABOUT MORTAR STRATEGIES

Most pharma companies track policy. Few have someone in Washington who can act on it.

Mortar Strategies is a bipartisan government relations and public affairs firm built for life sciences market access -- federal and multi-state. We work with biotech, medical device, and drug manufacturers who need coverage decisions moved, not just monitored.

That means direct engagement with CMS, Medicare Administrative Contractors, health plans, and PBMs. Coordinated strategy around ICER reviews before final determinations lock in. Knowing which state markets to enter first and which payer relationships get your product on formulary. And having someone who sees threats like these while there is still time to respond.

> **If something in this edition affects your product or your team's priorities, reply and tell us what you're watching.**
>
> No pitch. Just a conversation. Derek Jordan, Mortar Strategies: **derek@mortarstrategies.com**