PRESENTED BY MORTAR STRATEGIES

February 2026 Edition

In February: the most consequential federal PBM reform in history was signed into law, TrumpRx launched as a direct-to-consumer MFN pricing platform, four FDA approvals reshaped oncology and rare disease access, and the IRA Cycle 3 manufacturer participation deadline closed with universal sign-on.

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, PBM REFORM & NEGOTIATION

Consolidated Appropriations Act 2026 Signed: Federal PBM Reform (February 3)

Most consequential federal PBM action in history; 100% rebate pass-through, flat-fee compensation, mandatory reporting

Update: On February 3, 2026, President Trump signed the Consolidated Appropriations Act, 2026, which includes landmark bipartisan PBM reforms drawn from the PBM Reform Act of 2025. Key provisions: 100% pass-through of manufacturer rebates and price concessions to ERISA group health plans; mandatory delinking of PBM compensation from drug prices in Medicare Part D, requiring flat-fee-only compensation for bona fide services at fair market value; mandatory semiannual reporting to plans of net drug spending, rebates, and spread pricing data; expanded any-willing-pharmacy access provisions effective 2028; and PBM classification as "covered service providers" under ERISA Section 408(b)(2), effective immediately. Most financial provisions take effect January 1, 2028.

Industry Impact: This is the most structurally significant federal PBM legislation ever enacted. The flat-fee compensation mandate eliminates rebate-volume-based incentives for formulary placement in Medicare Part D beginning 2028, fundamentally altering how manufacturers negotiate formulary access. The 100% rebate pass-through for ERISA plans compresses the gross-to-net gap in commercial markets. Manufacturers that rely on rebates as the primary lever for preferred formulary position must begin redesigning their Part D and commercial contracting strategies now.

TrumpRx Launches February 5

White House launches direct-to-consumer MFN drug platform with 5 manufacturers and 40 branded drugs at launch

Update: President Trump launched TrumpRx.gov on February 5, 2026, a direct-to-consumer website offering discounted drug prices aligned with Most Favored Nation benchmarks. At launch, the platform featured 40 branded drugs from the first five manufacturers to reach MFN pricing agreements with the administration: AstraZeneca, Eli Lilly, EMD Serono, Novo Nordisk, and Pfizer. GoodRx was the integrated pricing infrastructure partner at launch. The platform is cash-only with no insurance involvement. Additional manufacturers and drugs are expected to be added on a rolling basis as MFN agreements expand.

Industry Impact: TrumpRx creates a new direct pricing pressure on payer contracting, DTC strategy, and gross-to-net dynamics. A cash-pay channel at MFN prices bypasses PBMs and insurance entirely, creating a visible reference price that payers can cite in formulary and rebate negotiations. Manufacturers not yet on TrumpRx face both competitive pressure and the implicit threat of MFN agreement requirements. Commercial and Medicare market access teams should model the downstream contracting and formulary implications of the emerging MFN pricing floor.

GLOBE/GUARD Comment Deadline: February 23

Comments close on two mandatory Medicare MFN pricing models; 20,000+ stakeholder comments received

Update: The public comment period closed February 23, 2026 on CMS's two proposed mandatory Medicare MFN pricing models: GLOBE (targeting Medicare Part B, with an October 2026 proposed start) and GUARD (targeting Medicare Part D). Over 20,000 stakeholder comments were submitted. Both models would impose additional mandatory manufacturer rebates on top of IRA-negotiated prices for drugs not currently selected for negotiation, creating a second pricing pressure layer on non-selected drugs.

Industry Impact: GLOBE and GUARD, if finalized, would extend MFN pricing beyond TrumpRx's voluntary framework to mandatory rebates for drugs outside the IRA negotiation program. For manufacturers of non-selected high-spend Part B and Part D drugs, this represents a portfolio-level pricing risk on top of IRA negotiation exposure. The volume of comments signals intense industry and payer interest; CMS's response to comments will signal how aggressively these models move toward finalization.

IRA Cycle 3: Manufacturer Participation Deadline February 28

Statutory deadline for all 15 selected Part B/Part D manufacturers to sign negotiation agreements

Update: February 28, 2026 was the statutory deadline for all 15 manufacturers of drugs selected for the third IRA negotiation cycle (IPAY 2028) to sign participation agreements with CMS. This was the critical internal month for manufacturer legal, pricing strategy, and evidence preparation before the March 1 data submission deadline. CMS confirmed on March 13 that all 15 manufacturers signed on.

Industry Impact: February was the last window for manufacturers to assess litigation, withdrawal, and engagement strategy before the data submission deadline locked in their negotiation posture. With all 15 ultimately participating, the February deadline effectively closed the final strategic off-ramp for affected manufacturers. Teams should now be fully engaged in IPAY 2028 counter-offer and negotiation preparation through Fall 2026.

IRA Cycle 1 MFPs: First Full Month of Real-World Claims Data

January 1 effectuation of MFPs on 10 drugs; February was the first complete month of claims flow through the Medicare Transaction Facilitator

Update: January 1, 2026 marked the first-ever effectuation of IRA Maximum Fair Prices on 10 selected Part D drugs. February 2026 was the first complete calendar month of claims data flowing through the Medicare Transaction Facilitator, providing

manufacturers, plans, and PBMs with the first real-world signal of MFP impact on utilization patterns, formulary behavior, and net price dynamics.

Industry Impact: February's claims data is the first empirical baseline for modeling Cycle 3 negotiation dynamics and testing assumptions about how MFPs affect utilization and market share. Manufacturers with Cycle 3 drugs selected should incorporate this early data into their IPAY 2028 modeling. KFF's concurrent analysis confirmed that formulary access for the 10 negotiated drugs improved in 2026 relative to 2025 -- a counterargument to the prior concern that negotiated drugs would face payer access restrictions.

KFF: IRA Coverage Mandate Driving Formulary Improvement for Negotiated Drugs

9 of 10 first-cycle IRA drugs saw formulary coverage rate improvements in 2026 vs. 2025; statutory mandate confirmed working

Update: KFF published analysis on February 11, 2026 showing that 9 of the first 10 IRA-selected drugs saw formulary coverage rate improvements in 2026 relative to 2025, driven by the IRA's statutory requirement that all Part D plans cover all selected drugs including all dosage forms and strengths. In 2026, all Part D enrollees have coverage of all 10 negotiated drugs. Some drugs showed sharp access gains -- for example, Fiasp climbed from coverage availability for only 25% of enrollees to 100%.

Industry Impact: The IRA statutory coverage mandate is functioning as designed, creating uniform formulary access for negotiated drugs that did not previously exist. For Cycle 3 manufacturers, this is a meaningful market access signal: negotiation selection, while carrying significant pricing risk, also mandates formulary coverage across all Part D plans. Market access teams should factor this access guarantee into their IPAY 2028 commercial modeling.

GENEROUS Model: State and Manufacturer Engagement Intensifies

NASHP state-only webinar February 18; original March 31 manufacturer deadline still in effect; best price implications crystallizing

Update: The GENEROUS Model (Medicaid MFN pricing, launched January 2026) entered active engagement in February. NASHP hosted a state-only webinar on February 18 covering GENEROUS and BALANCE. The original March 31 manufacturer application deadline was still in effect during February (later extended to April 30 in early March). Supplemental rebate, best price, and portfolio-level pricing implications were actively crystallizing for manufacturers with Medicaid-dependent brands.

Industry Impact: The GENEROUS Model's best price and supplemental rebate implications were becoming clearer to manufacturers in February as state engagement sessions produced operational detail. Manufacturers with branded drugs in Medicaid must assess whether GENEROUS participation compresses their existing supplemental rebate arrangements and how MFN-aligned Medicaid net prices interact with their commercial pricing strategy before the final participation deadline.

FEDERAL

COVERAGE, PRIOR AUTHORIZATION & POLICY

2027 ACA NBPP Proposed Rule Published (February 9/11)

CMS proposes elimination of standardized plans; projects 1.2-2M enrollment reduction; commercial formulary implications

Update: CMS released the proposed Notice of Benefit and Payment Parameters for plan year 2027 on February 9-11, 2026. Key proposals include elimination of standardized plan options, expansion of catastrophic coverage eligibility, and introduction of non-network QHP certification. CMS projects the proposed rule would reduce ACA Marketplace enrollment by 1.2 to 2 million and reduce federal spending by up to $10.4 billion.

Industry Impact: Elimination of standardized plans removes a formulary floor that has constrained payer flexibility in the commercial Marketplace. Manufacturers of specialty drugs with significant individual market volume should model the formulary

tightening and specialty tier positioning risk for 2027 plan year launches. Reduced enrollment projections also signal a shrinking commercial Marketplace channel for manufacturers dependent on that coverage segment.

OPPS Drug Acquisition Cost Survey Active (Deadline March 31)

CMS's first-ever mandatory hospital drug acquisition cost survey live throughout February; 1,843 NDCs; 340B implications

Update: CMS's first-ever mandatory hospital outpatient drug acquisition cost survey -- covering 1,843 NDCs using July 2024 through June 2025 data -- was active throughout February 2026, with a March 31 response deadline. Survey results will directly inform CY 2027 OPPS drug reimbursement policy, making this a critical Part B/hospital outpatient drug pricing lever. Non-response strategies, certification compliance risks, and 340B pricing interaction questions were active issues for hospital systems and their manufacturer partners.

Industry Impact: The OPPS drug acquisition cost data will be the first empirical basis for CMS to reset hospital outpatient drug reimbursement below current ASP-based rates. Manufacturers of drugs with significant HOPD volume should monitor how survey data translates into CY 2027 OPPS payment rates and assess the 340B pricing interaction implications of any OPPS payment adjustments.

Medicaid State Directed Payment Guidance: OBBBA SDP Caps Implemented (February 2)

CMS Dear Colleague Letter implements SDP caps at 100% of Medicare rates for expansion states; safety-net hospital implications

Update: CMS issued a Dear Colleague Letter on February 2, 2026 implementing revised Medicaid State Directed Payment guidance under OBBBA Section 71116, capping SDPs at 100% of Medicare rates for Medicaid expansion states and 110% for non-expansion states, covering inpatient and outpatient hospital, nursing facility, and academic medical center services. The letter clarified grandfathering timelines for legacy SDP arrangements.

Industry Impact: Safety-net hospitals dependent on SDPs to bridge the gap between Medicaid reimbursement and cost will face direct revenue pressure as caps take effect. Manufacturers with significant institutional Medicaid volume through safety-net hospitals and AMCs should model network adequacy implications as those institutions face reduced Medicaid revenue, particularly in non-expansion states where the 110% cap still represents a significant cut from prior SDP levels.

WISeR AI PA Model: Survival Confirmed, First Full Operational Month

CAA 2026 signed without defunding amendment; February was first complete month of WISeR coverage in 6 states

Update: The Consolidated Appropriations Act 2026 was signed without the House-passed amendment to defund the WISeR AI Prior Authorization Model, confirming its survival. February 2026 marked the first complete operational month of WISeR for services covered from January 15 in 6 states. KFF published an impact analysis on February 10. Provider pushback, portal compliance friction, and Part B specialty drug access disruption risks became quantifiable for the first time.

Industry Impact: WISeR's survival in the appropriations process signals CMS has regulatory backing to expand the model. For manufacturers of Part B physician-administered drugs, February's operational data is the first evidence of how AI-driven PA affects access timelines, denial rates, and physician ordering behavior. Teams should obtain WISeR denial data by HCPCS code for affected products and begin building the access impact case that will be needed for legislative or regulatory challenges in 2026.

FEDERAL

FDA APPROVALS

FDA Approves Pembrolizumab + Paclitaxel for Platinum-Resistant Ovarian Cancer (February 10)

First PD-1 regimen with OS benefit in this population; PD-L1 companion diagnostic required; KEYNOTE-B96

Update: The FDA approved pembrolizumab (Keytruda, IV and subcutaneous Keytruda Qlex) in combination with paclitaxel, with or without bevacizumab, on February 10, 2026 for adult patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal carcinoma whose tumors express PD-L1 (CPS 1 or higher) and who have received one to two prior systemic regimens. The FDA simultaneously approved the PD-L1 IHC 22C3 pharmDx assay as a companion diagnostic. Approval was based on KEYNOTE-B96 (n=643), which demonstrated median PFS of 8.3 vs. 7.2 months (HR 0.72) and median OS of 18.2 vs. 14.0 months (HR 0.76) in the PD-L1 CPS 1+ population.

Industry Impact: This is the first PD-1 inhibitor regimen to demonstrate an OS benefit in platinum-resistant ovarian cancer, requiring payers to build new oncology pathway criteria for a checkpoint inhibitor indication that previously lacked regulatory validation. The PD-L1 companion diagnostic requirement also creates CDx coverage obligations that payers must address simultaneously with the therapy coverage determination. HOPDs and oncology practices must update clinical pathways and PA criteria immediately.

FDA Approves Acalabrutinib + Venetoclax for First-Line CLL (February 19)

First all-oral, fixed-duration regimen for previously untreated CLL; AMPLIFY trial; 3-year PFS 77% vs 67%

Update: The FDA approved acalabrutinib (Calquence, AstraZeneca) in combination with venetoclax (Venclexta, AbbVie/ Genentech) on February 19, 2026 for the first-line treatment of adults with CLL or SLL. This is the first and only all-oral, fixed-duration combination regimen for previously untreated CLL. Approval was based on the phase 3 AMPLIFY trial (n=581), which demonstrated superiority over investigator's choice chemoimmunotherapy (FCR or BR) in patients without del(17p) or TP53 mutation: 3-year PFS rate 77% vs 67%; median PFS not reached vs 47.6 months (HR 0.65).

Industry Impact: The first all-oral, fixed-duration first-line CLL approval creates immediate BTK inhibitor sequencing displacement and fixed-duration coverage and access criteria development requirements for payers. The 14-month fixed treatment duration is a meaningful budget impact advantage over indefinite continuous BTK inhibitor therapy. Payers must build first-line CLL pathways that now include a fixed-duration oral option alongside continuous ibrutinib and acalabrutinib monotherapy. Competing hematology brands should assess formulary renegotiation exposure.

FDA Approves Yuviwel (Navepegritide) for Achondroplasia in Children (February 27)

First once-weekly CNP analog for achondroplasia in children ages 2+; accelerated approval; competes with daily vosoritide

Update: The FDA granted accelerated approval to Ascendis Pharma's Yuviwel (navepegritide) on February 27, 2026, the first and only once-weekly treatment to increase linear growth in children 2 years and older with achondroplasia with open epiphyses. Approval was based on the phase 3 ApproaCH trial (n=84), demonstrating improved annualized growth velocity. A Rare Pediatric Disease Priority Review Voucher was granted. Continued approval is contingent on confirmatory trial results. Commercial availability was expected in early Q2 2026. Yuviwel competes directly against daily vosoritide (Voxzogo), approved in 2021.

Industry Impact: The once-weekly dosing creates a direct convenience differentiator against daily vosoritide, forcing payers to make a new coverage and step therapy determination in achondroplasia for the first time since 2021. The accelerated approval pathway creates coverage-with-evidence-development questions, and the rare pediatric disease population requires specialized genetic testing coverage, specialty pharmacy channel setup, and growth velocity monitoring criteria. Market access teams must build the once-weekly vs. daily clinical and economic case immediately.

FDA Approves Bysanti (Milsaperidone) for Schizophrenia and Bipolar I Disorder (February 20)

New chemical entity atypical antipsychotic; active metabolite of iloperidone; Q3 2026 commercial launch planned

Update: The FDA approved Vanda Pharmaceuticals' Bysanti (milsaperidone) on February 20, 2026, a new chemical entity atypical antipsychotic that rapidly interconverts to iloperidone (Fanapt), for the treatment of schizophrenia and acute manic or mixed episodes associated with bipolar I disorder in adults. Bysanti demonstrated bioequivalence to iloperidone across the therapeutic dosing spectrum, enabling reliance on iloperidone's established clinical development program and more than 100,000 patient-years of real-world experience. Commercial availability is planned for Q3 2026. Data exclusivity extends through February 20, 2031.

Industry Impact: Bysanti enters the heavily genericized six protected class antipsychotic market where formulary placement for branded entrants is determined primarily by step therapy, Medicaid behavioral health formulary design, and long-acting injectable differentiation. Market access strategy centers on establishing step therapy sequencing against generic iloperidone, Medicaid preferred drug list positioning, and differentiating from the reference compound through the NCE regulatory status and data exclusivity. The Q3 2026 commercial launch timeline creates an immediate access strategy buildout requirement.

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

Federal PBM reform is now law -- contracting strategy must change. TrumpRx has created a visible MFN reference price. IRA Cycle 3 negotiations are locked in. 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**