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May 2026 Edition

In May alone: the Supreme Court closed the last legal exit on IRA negotiations, CMS launched its GLP-1 Medicare demonstration, Nebraska began enforcing Medicaid work requirements, and the comment window on the most significant drug prior authorization rulemaking in years closes in 14 days.

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

Medicare GLP-1 Bridge Launches July 1 at $50/Month Copay

First-ever federal anti-obesity drug coverage in Medicare Part D

Update: CMS confirmed the Medicare GLP-1 Bridge (Section 402 demonstration) launching July 1, 2026 through December 31, 2027. Part D beneficiaries with BMI 35 or higher, or BMI 27 or higher with qualifying comorbidities, can access Wegovy, Foundayo, and Zepbound (KwikPen) at a flat $50/month copay. Manufacturers agreed to a net price of $245/month. The Bridge runs outside standard Part D, meaning the copay does not count toward TrOOP or the annual out-of-pocket cap.

Industry Impact: Medicare is now a direct access channel for anti-obesity GLP-1s for the first time. Market access teams must rapidly address new formulary structures, manufacturer participation terms, and utilization management criteria. The Bridge's separation from Part D benefit flow also creates novel implications for rebate and net price strategy.

Supreme Court Allows IRA Medicare Drug Price Negotiation to Stand

Court declines pharma challenge, locks in CMS authority

Update: The Supreme Court declined in May 2026 to hear challenges from AstraZeneca, Boehringer Ingelheim, Bristol Myers Squibb, Janssen, Novartis, and Novo Nordisk. CMS authority over the Medicare Drug Price Negotiation Program is now intact with no remaining primary legal avenue to block negotiations.

Industry Impact: All manufacturers in the third negotiation cycle (IPAY 2028) must now fully engage. First-cycle MFPs took effect January 1, 2026 at 38-79% discounts off 2023 list price and are locked in. The legal off-ramp is gone.

CMS Opens IRA Cycle 3 Negotiations: First-Ever Part B Drugs in Play

15 Part B and Part D drugs in active negotiation; prices effective January 1, 2028

Update: CMS selected 15 high-cost drugs for IPAY 2028 on January 27, 2026 -- the first cycle to include drugs payable under Medicare Part B alongside Part D products. All 15 manufacturers confirmed participation by the February 28 deadline. Negotiations are active through Fall 2026, with MFPs due November 30 and prices taking effect January 1, 2028. Combined Medicare spending on the 15 selected drugs was approximately $27 billion in the prior 12-month period.

Industry Impact: The Part B inclusion extends federal pricing pressure into physician-administered specialties and oncology for the first time. Manufacturers, HOPDs, and oncology clinics must now model IPAY 2028 portfolio exposure. With the legal challenges dead, preparation is the only viable posture.

Trump Administration Expands TrumpRx Discount Program to Generic Drugs

Federal coupon initiative extended beyond branded drugs; 600+ generics added

Update: The TrumpRx program, which connects consumers with direct manufacturer discount coupons, was expanded to over 600 generic drugs in May 2026, targeting uninsured individuals and high-deductible plan enrollees.

Industry Impact: Commercially insured patients face significant friction due to accumulator and maximizer programs blocking coupon credits toward out-of-pocket maximums. TrumpRx is not a substitute for formulary access strategy.

FEDERAL

COVERAGE & PRIOR AUTHORIZATION

CMS Proposes Electronic Prior Authorization Modernization for Drug Coverage

FHIR-based API workflows and drug-specific PA timelines proposed; comment period open

Update: CMS published proposed rule CMS-0062-P on April 10, 2026, proposing to extend electronic prior authorization requirements to prescription drugs -- a gap left by the 2024 CMS-0057-F final rule, which covered only non-drug items and services. The rule would require impacted payers (Medicare Advantage, Part D, Medicaid managed care, and QHP issuers on the FFE) to support FHIR-based electronic PA, establish 24-hour urgent and 72-hour standard decision timelines, mandate denial transparency, and publicly report PA metrics. If finalized, most requirements take effect October 1, 2027. Comments close June 15, 2026.

Industry Impact: Faster, standardized PA reduces time-to-therapy for high-cost specialty drugs. The simultaneous Senate push to restrict CMS's WISeR AI PA model signals continued volatility in the PA landscape through 2027.

Senate Democrats Move to Restrict CMS's AI Prior Authorization Model (WISeR)

Legislation introduced to limit automated PA reviews

Update: Senate Democrats introduced legislation in late May 2026 to repeal or restrict the WISeR AI Prior Authorization Model, following complaints from medical societies about erroneous denials and access delays for physician-administered drugs.

Industry Impact: If advanced, this directly affects PA timelines for specialty and Part B drugs. Manufacturers of biologics and oncology therapies should monitor; the outcome shapes whether AI-assisted PA accelerates or delays access.

ACTION REQUIRED: JUNE 15 DEADLINE

Comment Period Closes: CMS Drug PA Proposed Rule (CMS-0062-P)

The most consequential open rulemaking window for specialty drug access in 2026

Update: The comment period for CMS-0062-P closes June 15, 2026. This proposed rule would extend electronic PA requirements to prescription drugs for the first time across MA, Part D, Medicaid managed care, and FFE QHPs. It sets 24-hour urgent and 72-hour standard decision windows, mandates FHIR-based electronic PA, and requires public reporting of PA metrics. Most provisions would take effect October 1, 2027 if finalized.

Industry Impact: This rule will govern PA infrastructure for the majority of commercially relevant covered lives. Manufacturers of biologics, oncology therapies, and Part B physician-administered drugs should submit comments documenting PA denial rates, time-to-therapy delays, and operational barriers before June 15.

CMS Finalizes 2027 ACA Marketplace Benefit and Payment Parameters

Plan design, affordability, and Essential Health Benefits rules updated

Update: CMS finalized the 2027 NBPP in May 2026, reducing federal user fees, adding rate-filing transparency requirements, and updating EHB rules against a backdrop of higher premiums following 2026 enhanced subsidy expiration.

Industry Impact: A KFF survey found 51% of Marketplace enrollees report significantly higher costs this year. Payer pushback is intensifying, with tighter medical necessity criteria and broader formulary exclusions expected in Q3 2027 plan design cycles.

FEDERAL

DEVICE & MEDTECH ACCESS

CMS and FDA Advance RAPID Pathway for Breakthrough Device Coverage

Accelerated Medicare coverage track proposed; NTAP alternative pathway targeted for elimination

Update: CMS and FDA jointly advanced the RAPID pathway in Spring 2026, offering accelerated Medicare coverage for breakthrough-designated devices. CMS simultaneously proposed eliminating the NTAP alternative pathway for inpatient payment add-ons.

Industry Impact: RAPID compresses the FDA-to-Medicare coverage lag, a historically critical barrier for device market access. But the NTAP elimination raises the evidentiary bar for inpatient add-on payments, partially offsetting the speed advantage.

FEDERAL

FDA APPROVALS

FDA Grants Accelerated Approval to Gilead's Hepcludex for Chronic HDV

First and only approved treatment for hepatitis delta virus in the U.S. (approved May 22, 2026)

Update: The FDA granted accelerated approval to Gilead's Hepcludex (bulevirtide-gmod) for adults with chronic HDV, the first and only approved HDV therapy in the United States.

Industry Impact: Payers must build coverage criteria from scratch for a previously untreatable orphan population. Market access teams face immediate work on orphan tiering, specialty distribution, and coding, with coverage-with-evidence-development restrictions possible pending full approval.

FDA Approves AstraZeneca's Durvalumab for High-Risk Bladder Cancer

Imfinzi approved in combination with BCG for BCG-naive NMIBC (approved May 28, 2026)

Update: The FDA approved durvalumab (Imfinzi) in combination with BCG for BCG-naive, high-risk non-muscle invasive bladder cancer, expanding an already-approved oncology label.

Industry Impact: Payers will rapidly update clinical pathways for a 13-cycle regimen. HOPDs and oncology clinics must revise prior authorization criteria, step-therapy requirements, and budget impact models.

STATE

PBM REFORM & PHARMACY ACCESS

Tennessee Enacts FAIR Rx Act, Banning PBM Pharmacy Ownership

Divestiture of PBM-owned pharmacies required by July 1, 2028

Update: Tennessee enacted the FAIR Rx Act in May 2026, prohibiting PBMs from holding pharmacy licenses and requiring full pharmacy ownership divestiture by July 1, 2028.

Industry Impact: One of the most structurally aggressive state PBM interventions to date. Manufacturers distributing through PBM-owned specialty pharmacies in Tennessee must assess channel continuity through the divestiture deadline.

Record State Legislative Activity on PBM Transparency and White Bagging

May 2026 sessions close with nationwide PBM reform push; all 50 states now have PBM rules

Update: May 2026 legislative sessions produced a record volume of bills targeting PBM vertical integration, mandatory white bagging, spread pricing transparency, and MAC list update frequency. All 50 states now have some form of PBM regulation.

Industry Impact: Specialty biologic manufacturers distributing through white bagging arrangements face growing site-of-care compliance complexity. State-by-state distribution network mapping is now required through the remainder of 2026.

Virginia Governor Vetoes PDAB Legislation, Signs PBM Accountability Bills

Mixed signal on drug affordability board model

Update: Virginia Governor Spanberger vetoed Drug Pricing Advisory Board legislation on May 19, 2026, while signing a separate package of PBM accountability, drug copay cap, and pricing transparency enforcement bills.

Industry Impact: A significant signal that PDABs face resistance even in favorable political environments. The signed PBM bills create immediate compliance obligations; Virginia's enforcement posture will be a leading indicator for other state markets.

CMS Proposes to Cap Medicaid State Directed Payments at Medicare Rates

Major structural shift in supplemental provider payment

Update: On May 20, 2026, CMS proposed capping Medicaid state-directed payments at 100% of Medicare rates for expansion states and 110% for non-expansion states, with a 10% annual phase-down for legacy SDPs starting in 2028 and a ban on future uniform-increase payment methodologies.

Industry Impact: A fundamental shift in safety-net hospital and managed care Medicaid financing. Manufacturers dependent on hospital and specialty clinic Medicaid volume should model network adequacy implications, particularly in non-expansion states.

Nebraska First to Enforce Medicaid Work Requirements Under OBBBA

50-state rollout begins; CBO projects up to 11.8 million coverage losses by 2034

Update: Nebraska began enforcing Medicaid community engagement requirements on May 1, 2026 under the One Big Beautiful Bill Act. Most non-elderly, non-disabled adults must document 80 hours/month of work, education, or community service. CBO projects up to 11.8 million coverage losses by 2034 across all OBBBA Medicaid provisions.

Industry Impact: Medicaid volume erosion in behavioral health, infectious disease, and primary care is the near-term risk. Manufacturers should model state-by-state beneficiary loss scenarios before broader enforcement defines the compliance architecture.

State Medicaid GLP-1 BALANCE Model Applications Open Through July 31

CMS accepts state Medicaid applications for negotiated GLP-1 coverage

Update: The Medicaid component of the BALANCE Model went live May 1, 2026, with CMS accepting state applications for negotiated GLP-1 coverage paired with lifestyle support through July 31, 2026. Participating states receive CMS-negotiated pricing under the GENEROUS CMMI model.

Industry Impact: Uneven state participation creates a fragmented Medicaid access map for obesity and metabolic treatments. Manufacturers must assess whether BALANCE/GENEROUS coverage terms are more favorable than existing state supplemental rebate agreements.

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

IRA Cycle 3 negotiations are live. The PA comment window closes in 14 days. Work requirements are already stripping Medicaid volume. None of this waits for your next quarterly review.