Navigating Market Access with Magnolia

2026 Health Policy Update: Key Developments in Washington and the Outlook for 2027

July 23, 2026

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Today's Moderators and Speakers

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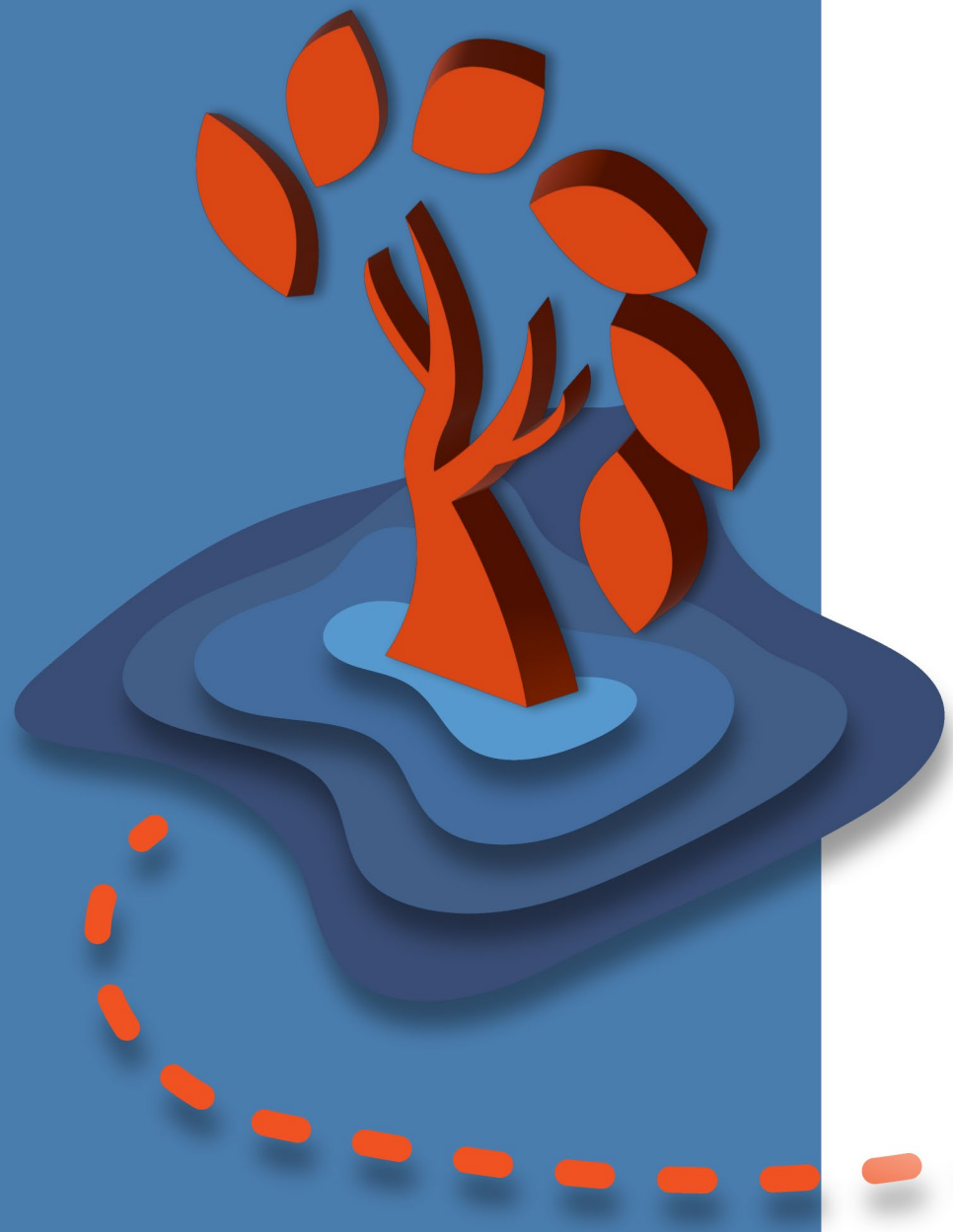

Agenda

1. Mid-Year Policy Update
2. 2027 Projections
3. The Pets of MMA
4. Wrap-Up

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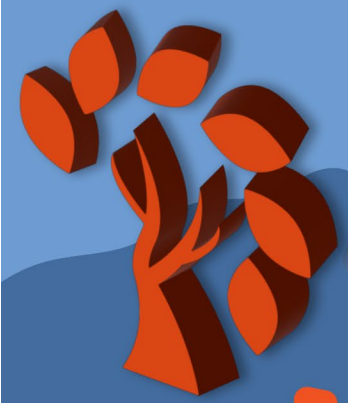
Mid-Year Policy Update



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The Drug Pricing Landscape: International Pricing and Tariffs

MFN pricing has prompted mixed reactions: supporters cheer the potential to lower U.S. drug costs, critics warn of reduced investment and access challenges

MFN Agreements

- On April 2, 2026, President Trump issued a Proclamation imposing 100% tariffs on imported patented drugs and their ingredients[1]
  - Exemption for companies that signed an MFN pricing agreement, agreeing to tie their drug prices to international prices.
  - 17 manufacturers have announced agreements, with limited details publicly disclosed[2]

GLOBE & GUARD

- GLOBE & GUARD would require drug companies to pay Medicare rebates from 2026-2031 when prices for certain Part B or D drugs are higher than in 19 OECD countries
  - GLOBE is set to launch on Oct 1, 2026. CMS has not indicated any delay, though the model did not reach OMB until June 26, 2026
  - GUARD is set to launch Jan 1, 2027, and reached OMB on June 15, 2026[3,4]
  - A mandatory CMMI model must have its final rule clear the White House and be published roughly 30 to 60 days in advance of its launch date[5]

Ex-U.S. Reactions

- The UK agreed to pay more for new drugs, double its spending on new medicines, and cap government rebates from pharma companies for a 0% tariff on its exports[6]
- A formal trade investigation was launched over Germany's pricing, the U.S. threatening to impose tariffs[7]
- Switzerland is weighing options to increase payment for new drug launches, via cantonal taxes, decreased funding to other parts of the system, or allowing privately insured patients coverage for new drugs to avoid potential investigation[8]

MFN, Most Favored Nation; OECD, Organization for Economic Cooperation and Development; CMS, Centers for Medicare & Medicaid Services; OMB, Office of Management and Budget; CMMI, Center for Medicare and Medicaid Innovation

PBM Reform: Where Does It Go From Here?

What Happened?[1]

- On February 3, 2026, President Trump signed the CAA, introducing sweeping PBM reforms that strengthen transparency, reporting, and oversight
- Key provisions include:
  - 100% rebate pass-through
  - Required compensation disclosure
  - Reporting requirements PBMs must submit to plans on a quarterly or semiannual basis
  - Civil monetary penalty enforcement by the HHS Secretary for PBMs that fail to meet reporting requirements

What's Next?

- Since the CAA, momentum for additional reform has continued as policymakers seek to go beyond transparency requirements
  - Recent FTC settlements with CVS and ESI require purchases under TrumpRx to be counted toward MOOP and deductibles if a law is passed addressing impact on Medicaid rebates and 340B pricing
  - The DOL proposed an ERISA rule that would require PBMs of self-insured employer plans to disclose rebates, spread pricing, and other forms of compensation[2]
  - States have also enacted laws targeting vertical integration, though they have been met with swift PBM pushback[3]

CAA, Consolidated Appropriations Act; PBM, Pharmacy Benefit Manager; DOL, Department of Labor; ERISA, Employee Retirement Income Security Act

Is the 340B Rebate Model Happening?

HRSA may implement a 340B rebate model pilot program to test post-purchase rebates as opposed to upfront discounts

What Is It?

The pilot would allow some drug manufacturers to pay rebates to 340B covered entities after they purchase the drugs at their full WAC

Is It Happening?

- On May 27, 2026, HRSA submitted a "notice" to OMB, which remains under review
- On June 16, 2026, HRSA posted an ICR notice to OMB related to rebate model applications and implementation

Potential Implications

- Transparency regarding diversion and duplicate discounts
- According to the AHA, the model would place significant administrative burden on covered entities, resulting in costs far higher than HRSA is estimating

HRSA, Health Resources and Services Administration; WAC, Wholesale Acquisition Cost; ICR, Information Collection Request; OMB, Office of Management and Budget; AHA, American Hospital Association

Other Initiatives

Medicaid Work Requirement[1,2]

- The Medicaid IFR released on June 1, 2026, narrowed the medical frailty definition, raising concerns among stakeholder groups over the status of beneficiaries with chronic conditions
  - Self-attestation of medical frailty will be allowed in 2027, but will be limited in 2028 and beyond
- In response, 25 states filed a suit on June 29, 2026, alleging the IFR goes beyond statutory language and violates constitutional limits on federal spending authority

ASP Reporting[3]

- The CY 2026 PFS introduced ASP changes effective 2Q 2027 that require manufacturers to:
  - Provide certifications from bona fide service fee recipients that the fee is not passed through to another customer or client
  - Submit fair-market-value methodologies for bona fide service arrangements
  - Include reasonable assumptions disclosure in quarterly ASP submissions

State Medicaid Fraud and Funding Withdrawals[4]

- The Administration is withholding over $1 billion in Medicaid funding from California and Minnesota over alleged fraud
  - Over $867 million is being withheld from CA, and $199 million from MN
  - States allegedly filed claims for care provided to deceased individuals, billed multiple patients at once, and charged for services without proper documentation
- In the past, the government targeted bad actors/providers rather than cutting off federal Medicaid funding

IFR, Interim Final Rule; PFS, Physician Fee Schedule; ASP, Average Sales Price; BFSF, Bona Fide Service Fees

IRA: Changes in Patient Cost-Sharing Post-DPNP[1]

Deductibles Are Higher and More Common in MA-PDs

Average Deductible Increase (2025 to 2026)

PDP enrollees	+$53
MA-PD enrollees	+$143

MA-PD Enrollees in Plans with Any Drug Deductible

2025	2026
60%	82%

MA-PDs historically more likely to offer no drug deductible, but that is changing.

Shift from Copayments to Coinsurance in MA-PDs

Share of Enrollees Facing Coinsurance

Drug Type	Preferred-Brand Drugs		Non-Preferred Drugs	
	2025	2026	2025	2026
MA-PDs	27%	56%	56%	89%
PDPs	97%	97%	100%	100%

- In PDPs, coinsurance was already widespread; in 2026, 97% of enrollees face coinsurance for preferred brands and 100% for non-preferred drugs.

Median Coinsurance in 2026

Plan Type	Preferred-Brand Drugs (Median)		Non-Preferred Drugs (Median)		Specialty-Tier Coinsurance in 2026 (All Drugs)	
	PDPs	MA-PDs	PDPs	MA-PDs	PDPs	MA-PDs
Median Coinsurance	25%	21%	34%	38%	25%	28%

- Specialty-tier coinsurance remains somewhat higher in MA-PDs—28% vs. 25% in PDPs—although both are slightly below or similar to 2025 levels.

[1] Medicare Part D Enrollment, Premiums, and Cost Sharing in 2026, https://www.kff.org/medicare/medicare-part-d-enrollment-premiums-and-cost-sharing-in-2026/

IRA: Opportunities to Submit Comments

Combo Drugs Under DPNP[1]

- CMS proposed a policy change for considering combination drugs under the Medicare DPNP to prevent manufacturers from adding a new ingredient, formulation, or administration route to avoid negotiation
- If CMS determines that a combination product differs from one of the selected drugs because the manufacturer added another active ingredient, it will consider the product part of the same qualifying drug as the original active ingredient drug negotiation
- The comment period on this proposed rule ends August 17, 2026

Part B Effectuation[2]

- CMS released draft guidance for 2028 Part B Effectuation that includes operationalizing the MFP that applies to Medicare Part D drugs to Medicare Part B drugs
- Manufacturers with an MFP for 2028 would need to register by May 1, 2027, and set up voluntary onboarding for Part B providers
- The comment period on this proposed rule ends September 18, 2026

IRA, Inflation Reduction Act; DPNP, Drug Price Negotiation Program; MFP, Maximum Fair Price

Senate Finance Committee Drug Pricing RFI

On June 16, 2026, Senate Finance Democratic Committee members released an RFI on several proposals that seek to lower the cost of prescription drugs. Comments due August 17, 2026.

Lowering Drug Prices

- Expand Medicare drug price negotiations
  - Factor international prices into negotiations
  - Allow annual price negotiations for more drugs earlier in their lifecycles
  - Enhance Medicare inflation rebates
  - Remove blockbuster drug bailout and incentivize biosimilar competition
  - Subscription model for popular drugs to improve access and pricing

Enhancing Prescription Drug Affordability

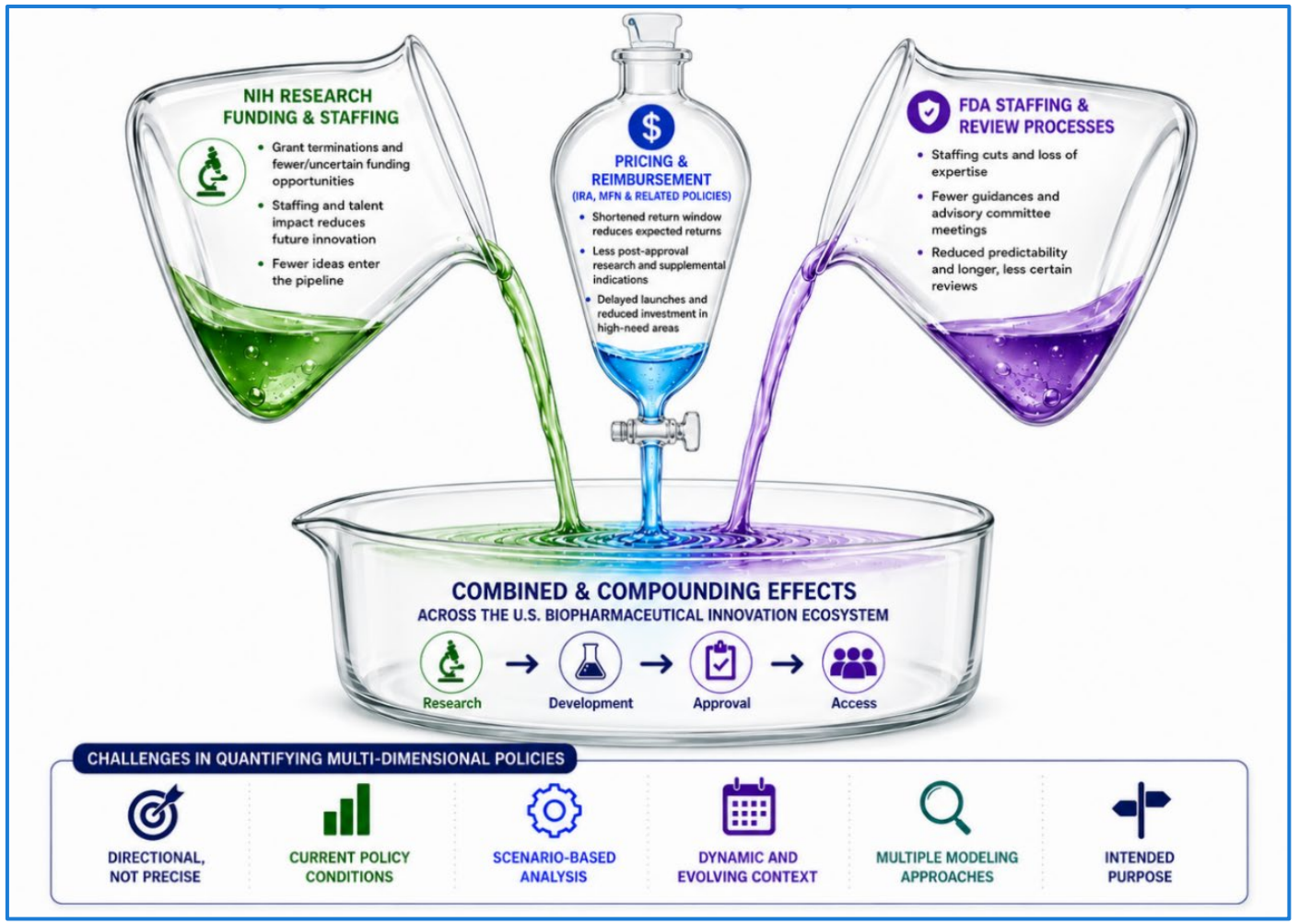
- Add OOP caps to more chronic care drugs
- Strengthen oversight of PBMs and health plans
- Reform generic drug reimbursement
- Expand eligibility for Part D LIS and contain Part D premiums
- Address pricing incentives across the prescription drug supply chain

Strengthening Biopharmaceutical Innovation in the U.S.

- Expand and create biomedical research funding and incentives
- Support high-risk and unmet-need drug development
- Increase clinical trial participation in the U.S.
- Cultivate scientific talent to enhance global competitiveness

RFI, Request For Information; OOP, Out-of-Pocket; PBM, Pharmacy Benefit Manager; LIS, Low-Income Subsidies

Senate RFI Creates an Opportunity to Identify and Address the Impact of Recent Changes on Innovation



- Magnolia assessed the combined impact of **funding, regulatory, and pricing policy changes** on future drug development[1]
- These findings provide **directional estimates** under current conditions rather than precise forecasts
- Evolving market dynamics, volatile revenue effects, and R&D funding shifts make **precise forecasting inherently difficult**
- Magnolia estimates that, over the next 20 years, these pressures could result in up to **660 fewer novel drugs reaching the market,** a **55% reduction**, and could affect up to **45% of drug indications** through both lost initial approvals and fewer label expansions

[1] Funded by the Biotechnology Innovation Organization (BIO).

2027 Proposed Rule Making

OPPS[1]

- CMS proposed reducing Medicare Part B reimbursement for 340B-acquired physician-administered drugs to ASP – 33.4%
  - Unlike in 2022 when the correct procedures were not followed, this time a drug acquisition cost survey was conducted before the cut was proposed
  - CMS proposes increasing the payment reduction from 0.5% to 3% to speed up remedy payback
- CMS also proposed expanding its ongoing site-neutral payment framework by adding a 60% reduction for non-contrast imaging services at excepted off-campus departments, aligning their rates with physician offices

IPPS[2]

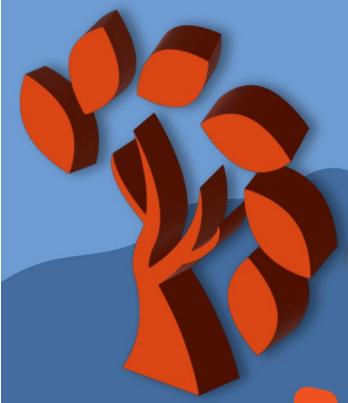
- CMS proposed applying a 0.17 payment adjustment to MS-DRG 018 cases involving clinical trial, expanded access, or other circumstances in which the hospital does not purchase the immunotherapy in the usual manner
- The proposed standard base payment for MS-DRG 018 would increase by approximately $22,000, or 6.9%, to about $335,900; increased the outlier payment by 28%
- Continues exclusion of no-cost and non-purchased product cases from the standard cost calculation, so they do not artificially reduce the MS-DRG weight and payment for commercially purchased therapies

MPFS[3]

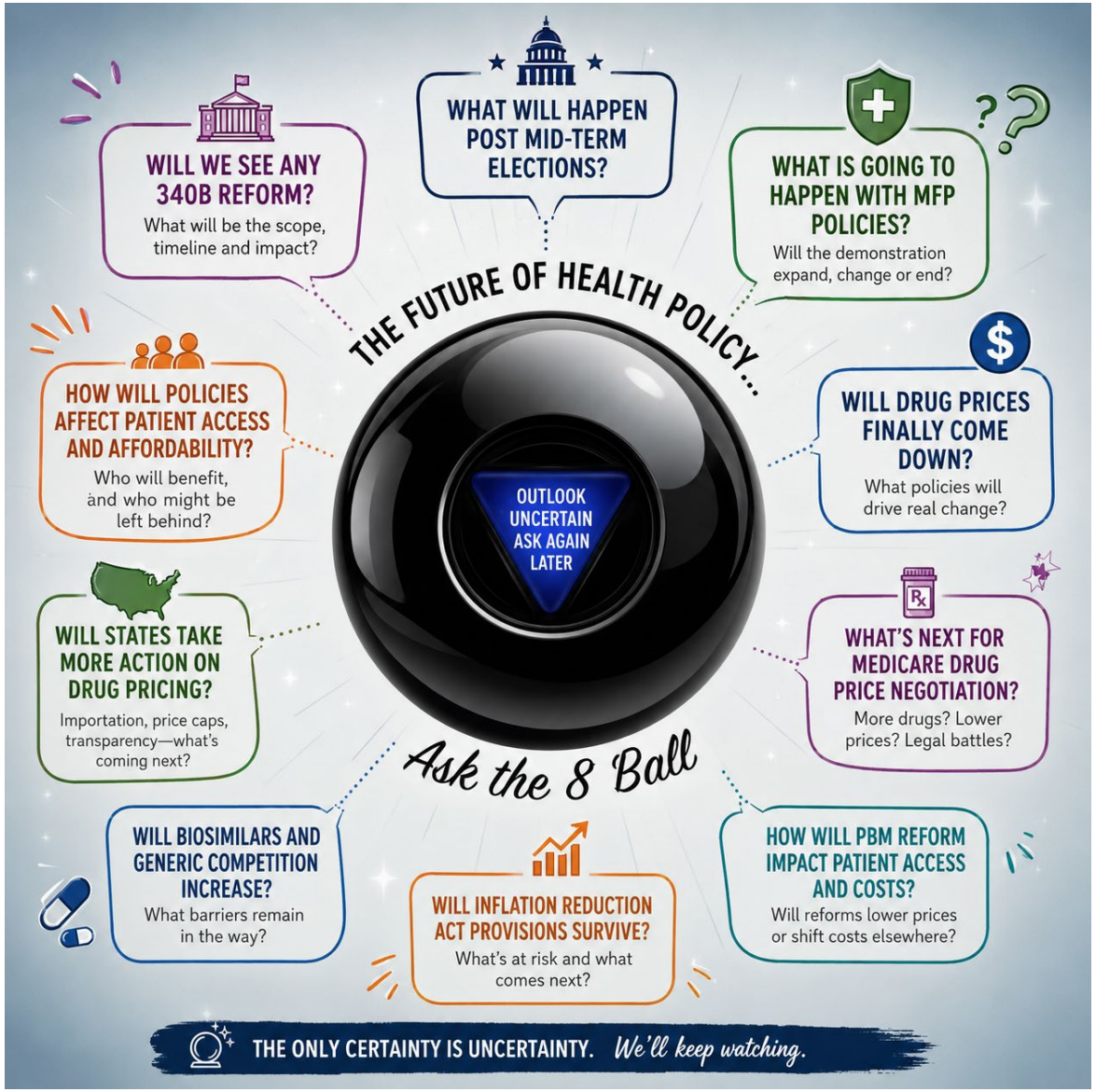
- CMS proposed conversion factors of $33.17 for qualifying APM participants and $32.84 for other clinicians, representing decreases of 1.19% and 1.68% from 2026 because the temporary 2026 payment increase expired
- CMS proposed continuing its overhaul of PE RVUs by reducing reliance on outdated survey data and moving toward more objective, regularly updated cost information
- CMS proposed replacing the fixed G2211 complexity add-on with percentage-based E/M modifiers, and a 50% payment reduction for certain same-day E/M visits furnished with global procedures

OPPS, Outpatient Prospective Payment System; IPPS, Inpatient Prospective Payment System; MS-DRG, Medicare Severity Diagnosis Related Group; MPFS, Medicare Physician Fee Schedule; APM, Alternative Payment Model; PE, Practice Expense; RVU, Relative Value Unit; E/M, Evaluation and Management

2027 Projections



Looking Ahead…



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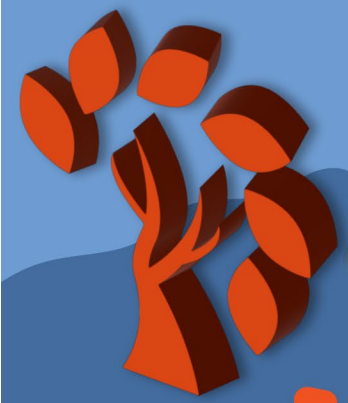
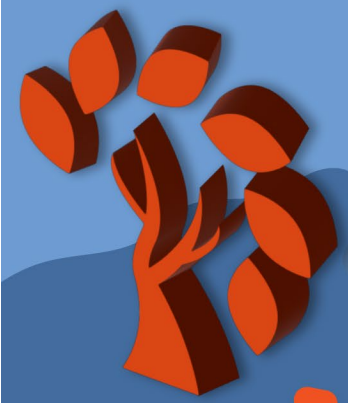
The Pets of MMA

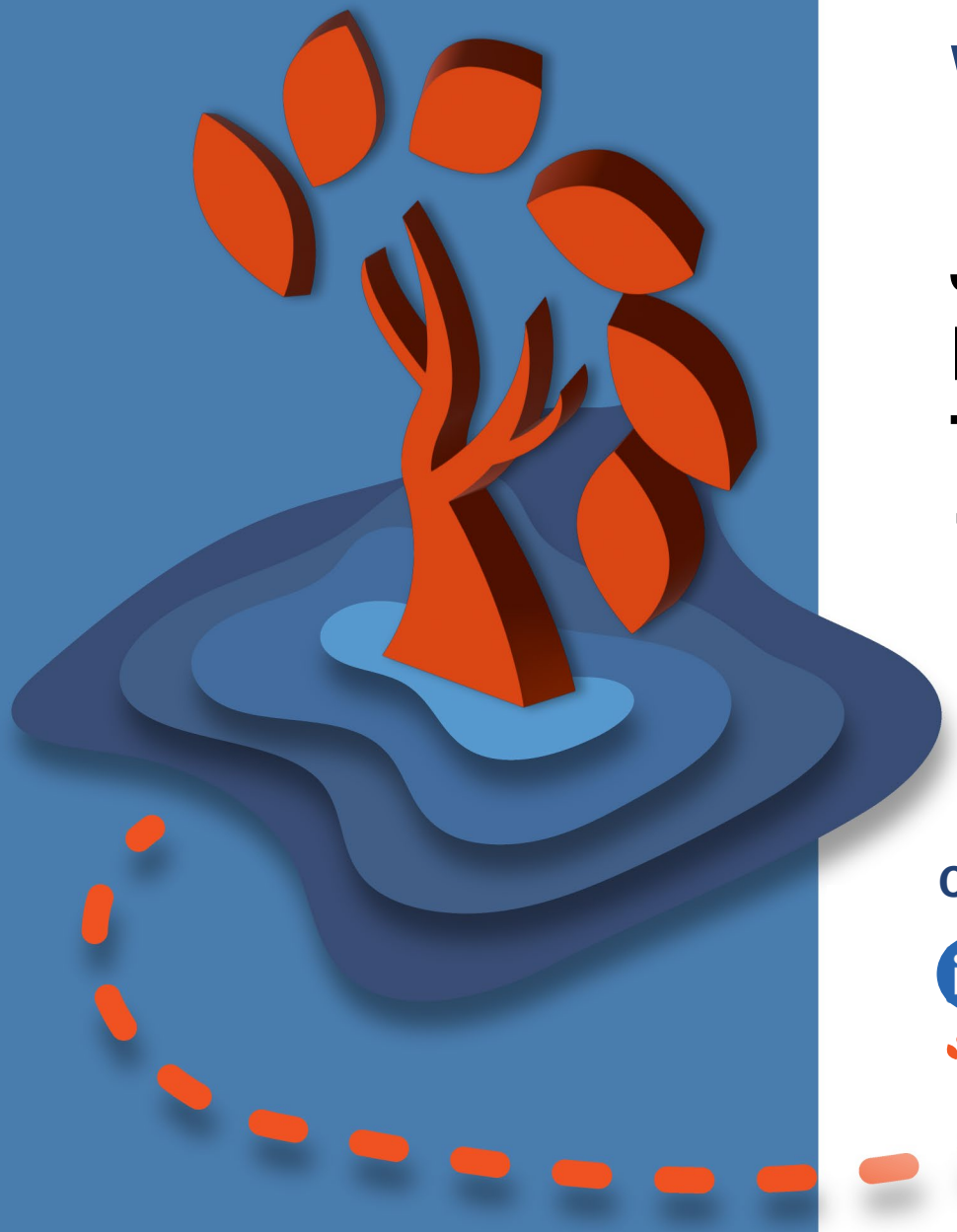


Barkley (a.k.a., Sparkly Barkley, Puddin' Pop)

- **Mother:** Amanda Forys
- **Age:** 10
- **Toxic Trait:** Punching you when you stop petting me
- **Likes:**
  - Wagging my nub
  - Speaking with a Southern accent
  - Talking about the Inflation Reduction Act
- **Dislikes:**
  - Being treated for cancer
  - Having to move more than 15 steps at a time
  - People talking about my rotund figure

Wrap-Up





We will be taking an August recess….

Join us for our next Navigating Market Access with Magnolia Thursday, September 24, 2026, 12:00 – 1:00 PM Eastern

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PEOPLE CAPABILITIES ACHIEVEMENTS INSIGHTS GLOBAL CITIZENSHIP

NEWSLETTER

Healthcare & Life Sciences: Drug Pricing Digest – Number 76

July 13, 2026

Our Drug Pricing and Market Access team tracks recent developments in healthcare reform, the Medicaid Drug Rebate Program, the 340B Program, Medicare, and state law.

THIS EDITION COVERS

- Inflation Reduction Act, Healthcare Reform, and General Developments
- Medicaid Drug Rebate Program (MDRP)
- 340B Program
- Medicare Part B
- Medicare Part D
- State Law Developments

Congratulations to Phil Perry on his retirement from Latham & Watkins! As part of his expansive career, Phil built a market-leading regulatory litigation practice in the healthcare and life sciences space, earning an extraordinary track record in some of the most complex matters in the field, including in 340B program litigation. Part of his legacy is the exceptional team he leaves behind.

Source: 340B Report.

Inflation Reduction Act, Healthcare Reform, and General Developments

CMS RELEASES PROPOSED 2027 HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM AND AMBULATORY SURGICAL CENTER RULE

The Centers for Medicare & Medicaid Services (CMS) released the calendar year 2027 Outpatient Prospective Payment System (OPPS) proposed rule, which was published in the Federal Register on July 7, 2026. The comment period ends on August 31, 2026.

Among other things, the OPPS proposed rule would reduce payment for drugs purchased under the 340B program to Average Sales Price (ASP) minus 33.4%, with no add-on payment. CMS cites the survey of hospitals that the agency conducted from January 1, 2026, through April 7, 2026, as a basis for this proposal, explaining that "we found that for drugs acquired through the 340B Program, hospitals' reported acquisition costs during the specified time period were approximately 33.4 percent below both the mean and the median ASP." CMS notes that "these results clearly demonstrate that ASP plus 6 percent is not an appropriate payment proxy for hospitals that acquire drugs through the 340B Program." For drugs with no ASP available, the proposed payment rate would be Wholesale Acquisition Cost (WAC) minus 33.4%.

The reduction in payment would result in a reduction of patient cost-sharing amounts. The savings resulting from the policy would be used to increase payments to providers for non-drug services.

Certain entity types would be exempt from the new 340B policy, including children's, critical access, and rural emergency hospitals. As part of implementing the new policy, CMS proposes to require providers to report the following two-letter modifiers on all drug claims:

- JG for drugs acquired under the 340B program by providers subject to the new payment policy
- TB for drugs acquired under the 340B program by providers exempt from the new payment policy
- XX for drugs not acquired under the 340B program

CMS proposes to rely on these modifiers when removing 340B utilization from manufacturer rebate invoices for Medicare Part B inflation rebates.

Sources: InsideHealthPolicy, PoliticoPro, BloombergLaw, BioWorld, Law360, PinkSheet, StatNews, 340B Report (first, second).

To subscribe to Latham & Watkins' Healthcare & Life Sciences: Drug Pricing Digest, email Chris Schott at:

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