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White House and Agency Agenda

March 31, 2026 / Elena Lynett and Aruna Vohra

Agenda

Administration and Agency Updates

Regulatory Update Including….

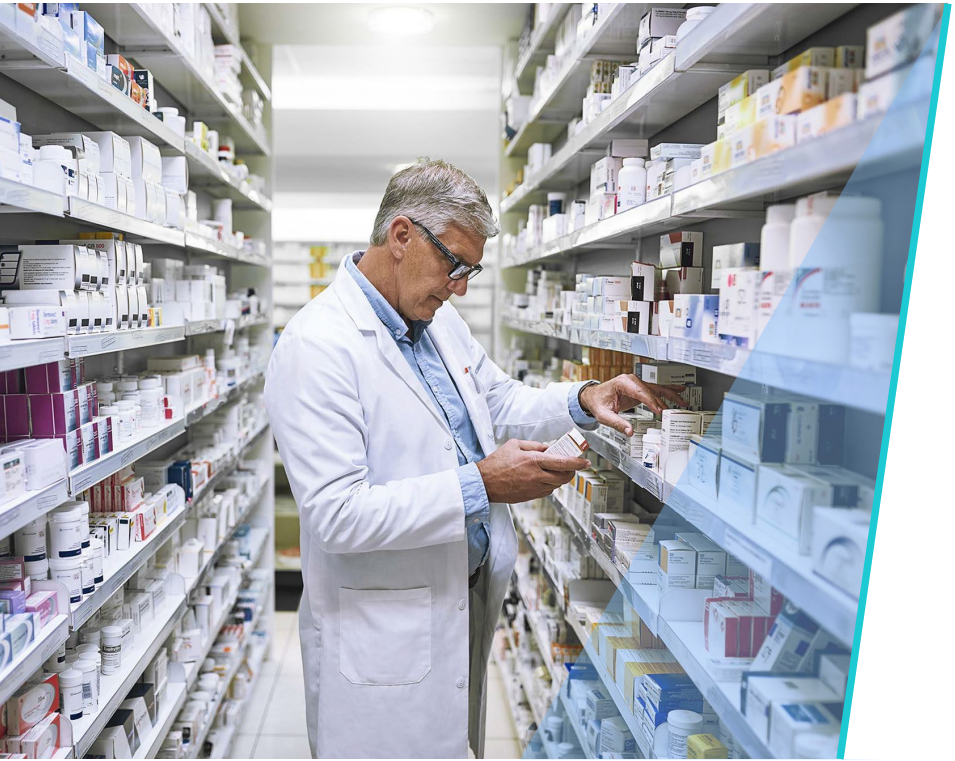
- **Transparency in Coverage**
- **Transparency Into PBM Fee Disclosures Proposed Rules**
- **Other Regulatory Updates**

Administration and Agency Updates

The Great Healthcare Plan

- Announced by White House January 15, 2026
- The Plan announces policies for lowering drug prices, lowering insurance premiums, holding big insurance companies accountable, and maximizing price transparency
- The plan does not specifically address extension of the enhanced premium assistance tax credits for ACA plans, which expired at the end of December 2025
- Some of the proposals included in the plan are already included in proposals the administration has released, including its most-favored-nation pricing proposals for Medicare Part B and D and new proposed rules for transparency in coverage. Other proposals in the plan would require legislative action
- Does not address ACA subsidy extension, but in State of the Union speech on February 24, President said that the goal was to bypass insurance companies and give individuals money directly so they can buy their own insurance

Most-Favored Nation Prescription Drug Policy



On December 22, 2025, the Administration proposed two Medicare pilot programs to reduce prices for both brand-name drugs and drugs administered at a provider's office

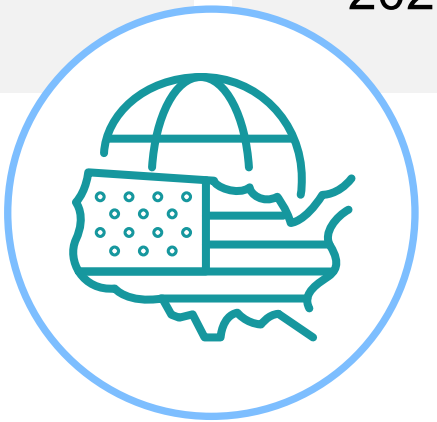
Both programs would have mandatory requirements to provide rebates to Medicare equal to the difference between prices in the US and an international benchmark based on what 19 other comparable countries pay

The President emphasized proposed MFN policy in recent speech at the World Economic Forum in Davos and stated that achieving lower prices through MFN policy would not have been possible without using tariffs as leverage

Most-Favored Nation Prescription Drug Policy

The Global Benchmark for Efficient Durg Pricing (GLOBE) Model would apply to Part B drugs administered by a physician, and would begin on October 1, 2026, if approved

The Guarding US Medicare Against Rising Drug Costs (GUARD) Model would apply to Part D retail drugs and would being on January 1, 2027, if approved



Most-Favored Nation Prescription Drug Proposals

Patient out-of-pocket costs would be tied to the international benchmark price

The models would be implemented in randomly selected geographic areas representing 25% of people who have a Medicare Part D plan or are in Medicare Part B

Comments on the proposals were due February 23, 2026

Most-Favored Nation Prescription Drugs

Aims to stop U.S. consumers subsidizing lower drug prices overseas

Drugmakers must offer U.S. patients lowest cost price available in other developed nations

Applies to single-source brand name drugs without generic or biosimilars

Agencies (CMS and HHS) to monitor manufacturer compliance and modify or revoke drug approvals if costs are not reduced

Impacts to Drug Benefit Design

Formulary strategy

- Must include MFN-compliance drugs and place in preferred tiers
- Specialty drugs may be excluded from MFN pricing
- Plans need to manage coverage criteria and prior authorizations

Cost-sharing

- Reduces coinsurance and copay amounts for participants
- Value-based designs with zero or reduced cost share

Impacts to Drug Benefit Design

Rebate contracting models

- Shift from rebate-driven to net-price driven models with rebate reduction or elimination
- Reduce need for complex rebate negotiations

Actuarial models

- Adjust for slower drug price growth and uncertainty in manufacturer behavior

Impacts to Drug Benefit Design

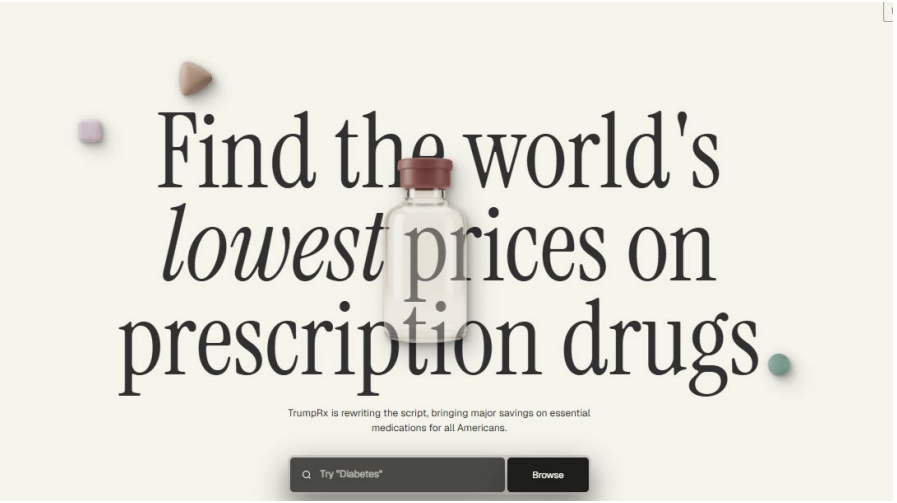
Medicare and Medicaid

- Temporary GLP-1 bridge program with reduced prices on GLP-1 drugs for obesity with comorbidities ($245 with beneficiary copay of $50/month) July 1, 2026 – December 31, 2026
- Interaction of this program vs. selected drug price negotiation
- Part D costs may decrease significantly as well as rebates due to the drug price negotiation

Trump Rx

Image source: trumprx.com

Trump Rx Went Live February 5, 2026



- Over 40 medications available through coupons or links to manufacturer direct-to-consumer pay sites, including GLP-1s and fertility medications
- More than half of medications are old brands with generics or generic alternatives
- Patients should not use the TrumpRx site without doing additional research

Trump Rx Cautions

Prices may be higher than plan copays

Cheaper alternative drugs or generics may be available

Some prices apply to starter doses and increase

Drugs do not pay rebates so price comparison to plan prices is difficult

Many PBMs offer lower cost consumer sites like GoodRx to their PBMs now

DTC Implications for Plans

- Provides options to participants with no coverage for weight loss (injectables and oral pills) and infertility drugs
- Potential opt-out behavior by participants
- However, plan participants with coverage may not see significant savings
  - Plan out-of-pocket costs generally lower than DTC cash prices
  - Doesn't count towards deductible or out-of-pocket maximums
  - Loss of drug data and concern for potential drug interactions

DTC Implications for Plans

Will Plans reimburse costs through Health Reimbursement Accounts?

- Some manufacturers require a statement of no insurance coverage available before providing the drugs

Coverage pressure from participants as prices drop

Benchmarking against federal pricing

Pressure on Plan formularies

- Expect PBMs to voluntarily cut pricing to Trump Rx levels without rebates

DTC Implications for Plans

Introduction of Carve-out programs

- Manufacturers bypass PBM programs to sell directly to plans
- Zepbound available through independent program administrators for $449/month
- Carve-out programs combine medical management with drug prescribing and dispensing

Trump Rx and Fertility Benefits

- Aimed to lower costs and expand access to In Vitro Fertilization (IVF)
- Trump Rx agreement with EMD Serono targets lowering prices ib certain fertility drugs
- CMS estimates that Trump Rx discounts may save up to $2200 per IVF cycle, however, each cycle can cost as much as $30,000 out-of-pocket. Patients may go through multiple cycles.

Trump Rx and GLP-1s

- Trump Rx agreement with Eli Lily and Novo Nordisk
- Discounted drugs include Ozempic and Wegovy and, as approved, Zepbound, Orforglipron, oral Wegovy or certain “similar” GLP-1s.
- Plans can work to negotiate MFN drug pricing for their own plans.
- In instances where Trump Rx pricing is more favorable, plans may consider alternative designs that provide access to GLP-1s for FDA approved uses.
- Compliance considerations should be reviewed with respect to benefit design and utilization management applied to GLP-1 plan benefits.

MAHA Report

On May 22, 2025, the Administration released the child health assessment report required by the Executive Order

Strategy released September 9, 2025

ACA Preventive Services Vaccines

- Changes in vaccine policy are causing confusion and have been generating questions
- On January 5, 2026, the CDC announced it would decrease the number of vaccines routinely recommended for all children from 17 to 11; recommend other vaccines for high-risk individuals, and recommend others through “shared clinical decision making”
- Although there have been shifts in the recommendations related to the pediatric vaccines and the COVID-19 vaccine, all vaccines remain on the U.S. preventive vaccine schedule
- Consequently, plans must continue to cover vaccines currently covered at the beginning of the plan year at least through this year

ACA Preventive Services: New Cervical Cancer Screening Guidelines

January 5, 2026, the Health Resources and Services Administration (HRSA) announced updated cervical cancer screening guidelines

Cervical cancer screening is recommended for average-risk women aged 21 to 65 years

High-risk Human Papillomavirus (hrHPV) testing is recommended for women ages 30-65. For women ages 21-29 cervical cytology (Pap) is recommended

The FDA has approved self-collection tests, so the recommendation is to permit patient-collected hrHPV testing for women aged 30-65

Plans must cover the new guidelines for the first plan year beginning on or after January 5, 2026. Generally, guidelines will apply to 2027

EBSA Enforcement Overhaul

- On January 15, 2026, the DOL's Employee Benef announced it is overhauling the enforcement prog areas:
  - Cybersecurity
  - Barriers to mental health and substance use dis
  - Protecting benefit distributions
  - Retirement asset management
  - Surprise billing
  - Criminal abuse of contributory benefit plans
- The agency will prioritize "serious misconduct rath

Monitoring Other EBSA Enforcement Developments

- On June 2, 2025, the U.S. Department of Labor (DOL) announced a significant expansion of its compliance assistance tools by launching an Opinion Letter Program across five key enforcement agencies, including the Employee Benefits Security Administration (EBSA). This initiative aims to provide employers, plan sponsors, and other stakeholders with clear, tailored guidance on complex issues related to employee benefit plans.
- July 22, 2025, House hearing, Restoring Trust: Enhancing Transparency and Oversight at EBSA

MHPAEA Nonenforcement Agreement

- On May 12th the court granted an abeyance (stay) based on the Departments stating it will reconsider the final regulations, including potentially issuing a proposed rulemaking rescinding or modifying the current regulations
- On May 15th the Departments issued a statement regarding enforcement of the 2024 MHPAEA final regulations. Specifically, the Departments indicate that they will not enforce the provisions of the 2024 Final Rule that were set to become applicable for plan years beginning on or after January 1, 2025 and 2026 or otherwise pursue enforcement actions, based on a failure to comply with those provisions that occurs prior to a final decision in the litigation, plus an additional 18 months
- The statutory provisions and 2013 final regulations remain in effect and enforceable

https://www.segalco.com/consulting-insights/mhpaea-litigation-and-enforcement-news

Regulatory Updates

DOL PBM Disclosure Proposed Rule

- DOL published a proposed rule on January 30, 2026, that would expand PBM disclosure obligations under ERISA's compensation disclosure provisions
  - Does not apply to governmental plans, but likely to influence enforcement
- Entities providing pharmacy benefit manager related services would be required to provide compensation disclosures to fiduciaries of ERISA-covered self-insured group health plans
  - Would include consultants providing advice, recommendations or referrals regarding PBM services
- Comments due April 15, 2026
- If finalized, would apply to plan years beginning on or after July 1, 2026

DOL PBM Disclosure Proposed Rule

- Disclosure would be required at initial retention, extension, or renewal, and semi-annually thereafter
- PBMs would have to disclose detailed information (next slide)
- Fiduciaries may request additional information
- Audit rights
  - Not less than once per year, at the written request of the plan
  - Plan fiduciary may select the auditor, without limitations by the PBM
  - Plan must pay expenses related to selection and retention of auditor, PBM pays cost of providing the information
  - PBM may not impose restrictions, such as location, period, or number of records

Proposed Disclosure at Initial Retention, Extension, or Renewal

1. Description of services
2. Direct compensation
3. Manufacturer payments
4. Spread compensation
5. Copay claw-backs
6. Price protection agreements
7. Compensation for termination of service contract or arrangement
8. Description of other compensation
9. Description of formulary placement incentives
10. Drug pricing methodology
11. Statement of fiduciary status
12. Statement of audit right

Proposed Semi-Annual Disclosure

1. Direct compensation
2. Manufacturer payments
3. Spread compensation
4. Copay claw-backs
5. Price protection agreements
6. Other compensation
7. Overage explanation
8. Statement of audit right

PBM Fee Disclosure – Why this Matters?

Enhanced fiduciary decision-making

- Greater visibility into true PBM cash flows
- Clarity on compensation received by brokers/consultants through association with a PBM
- Reduced reliance on potentially misleading rebate and fee structures during vendor selection and evaluation

PBM Fee Disclosure – Why this Matters?

Potential impact on negotiations

- Improved market competition among PBMs
- Plans may more accurately benchmark PBM compensation
- Contract terms focus more on direct, service-based pricing
- Reduce/eliminate PBM incentives tied to rebates/undisclosed fees
- Transparency could allow the contract structure to prioritize fiduciary goals of lower drug costs for plans and participants

Creditable Coverage Testing

Plans are required to issue notices of creditable coverage for Medicare eligible employees and retirees on whether their drug coverage is equal to or better than the Medicare Part D benefit

- Sent out prior to October 15th annually

A lifelong late enrollment part D penalty (LEP) may be incurred for Medicare-eligible active employees in a drug plan that is not creditable

Creditable Coverage Testing - 2027

Plans may need to perform additional testing to make this determination

- Actuarial equivalence testing or a simplified determination
- Earlier simplified method changed with new requirements
  - Reasonable coverage of brand name and generic prescription drugs and biologics
  - Reasonable access to retail pharmacies
  - Higher hurdle to meet or exceed the Medicare Part D value which has increased from 60% to 72%

Creditable Coverage Testing

Design passes the 60% threshold but not the 72% threshold:

- Plan Design passes 60% threshold
  - Medical and Rx combined Deductible $750
  - Coinsurance: Generic 25%; Preferred Brand 45%; Non-preferred brand 60%

- Plan Design Change needed to pass the 72% threshold
  - Medical and Rx combined Deductible $750
  - Coinsurance: Generic 15%; Preferred Brand 35%; Non-preferred brand 50%

CMS solicited comments on changes and potential impacts from parties including actuarial firms

Creditable Coverage Testing

Awaiting CMS guidance particularly on coverage of biological products and a definition of "reasonable" for coverage and pharmacy access

- Biological products are specialty medications derived from living organisms and generally used for complex conditions and injected or infused. These include monoclonal antibodies, vaccines, insulins and biosimilars. Treat conditions like rheumatoid arthritis, anemia, and cancer
- Do they include gene and cell therapy?

Transparency in Coverage Proposed Rule

Departments of Labor, HHS, and Treasury published the TiC proposed rule December 23, 2025; comments are due February 23, 2026

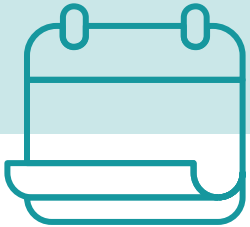
Transparency in Coverage Proposed Rule

Currently non-grandfathered plans must post Machine-Readable Files (MRF) for In-Network Rates and Out-of-Network Allowable Charges

Changes to MRF for non-grandfathered plans:

- Reduce the size of MRFs
- Timing for updating the MRFs changed to quarterly
- Reduce duplicative data for provider charges

Changes to machine-readable files would be effective twelve months after the rule is finalized

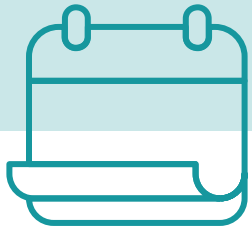


Transparency in Coverage Proposed Rule

Changes to **Internet-Based Price Comparison Tool** for all plans, both grandfathered and non-grandfathered

- Prices must be available via phone as well as the internet and paper
- New disclosure notice requirements

Would be effective for plan years beginning on or after January 1, 2027



New HIPAA Privacy Model

- In February 2026 HHS published a new HIPAA Privacy Model Notice templates
- The new templates are aimed help improve patient experience and understanding and are among other things aimed to assist health care entities on meeting **new requirements related to confidentiality of SUD patient records under the Part 2 Final Rule**
- The new templates includes:
  - **Model Notice of Privacy Practices for HIPAA Health Plan**
  - Model Notice of Privacy Practices for HIPAA Covered Health Care Provider
  - Model Part 2 Patient Notice
- Pans may review their current notices to ensure they have addressed all of the key elements

Regulatory Outlook

Regulations in the pipeline

Regulations updating the No Surprises Act Independent Dispute Resolution process

Guidance on offering fertility benefits

Additional Fertility Benefit Guidance Anticipated

Executive Order 14216, “Expanding Access to In Vitro Fertilization,” issued in February 2025, directed the Domestic Policy Council to submit a list of policy recommendations to protect IVF access and reduce out-of-pocket and health plan costs for IVF treatment

FAQ 72 Addressed Fertility Coverage

In October 2025, the Departments issued FAQ 72 addressing how plan sponsors can use existing law to offer fertility benefits

They are also considering whether to modify standards under which supplemental health insurance coverage can be expanded to include fertility coverage

Fertility Benefit Guidance

The FAQs noted expanded benefits:

- Similar to “cancer-only” or “hospital indemnity” plans, a fully insured fertility benefit can be offered as a limited excepted benefit if no coordination of benefits between the fertility benefit and the health plan
- Participants are not required to enroll in the health plan to receive access to the excepted fertility benefit
- This is not a self-insured fertility benefit

Fertility Benefit Guidance

Funds are interested in covering infertility treatment. Current options include:

- A dollar lifetime maximum benefit or coverage of bundled treatment cycles
- Limited excepted benefit EAP with coaching and navigation services to help participants understand their options
- An excepted HRA can reimburse out-of-pocket costs for fertility benefits
  - Maximum contribution to an excepted benefit HRA is $2,200 for 2026

Looking Ahead

Policy Themes

- Lower costs through market pressure and global benchmarking
- Reduce PBM/middlemen influence
- Consumer-directed healthcare and expansion of DTC drug purchasing
- Expanded transparency mandates
- Chronic disease prevention and reduction with obesity and metabolic health focus

Looking Ahead

Plans need to consider

- GLP-1 coverage strategy
- PBM audits and renegotiations
- Fiduciary risk mitigation
- Transparency compliance readiness
- Benefit redesign as needed


Thank you.
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Thank You and Questions