

# A Federal Update on Prescription Drug Policy

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# About PORTAL





**PORTAL** is an interdisciplinary research group based in the **Division of Pharmacoepidemiology & Pharmacoeconomics** at Brigham & Women's Hospital and Harvard Medical School.

We study the intersections between **evidence-based use, regulation, and affordability of prescription medications**, and publish on a variety of topics in these areas.



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# PORTAL's State Involvement

**PORTAL has provided support to various state-level health policy bodies:**

- National Academy for State Health Policy (NASHP) PDAB Working Group
- Colorado PDAB
- Oregon PDAB
- Washington PDAB
- Massachusetts Health Policy Commission

**Examples of this state-level support:**

- Preparing white papers and memos related to essential topics for PDABs
- Providing technical assistance and feedback on methods for data collection, analysis, and visualization.
- Presenting to Board members and staff on relevant issues in prescription drug policy





# Policy Overview





# Executive Actions on Prescription Drugs



1. EO 14221. Making America Healthy Again by Empowering Patients with Clear, Accurate, and Actionable Healthcare Information. February 2025.  
2. EO 14723. Lowering Drug Prices by Once Again Putting Americans First. April 2025.  
3. EO 14293. Regulatory Relief to Promote Domestic Production of Critical Medicines. May 2025.  
4. EO 14297. Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients. May 2025  
5. Sachs R. Administration Lays Out Drug Pricing Plan Through Executive Order. Health Affairs Forefront. April 2025.





# Congressional Action on Drug Pricing

On July 3, Congressional Republicans passed a budget reconciliation package, **H.R.1 – The One Big, Beautiful Bill Act (OBBB)**.<sup>1,2</sup>

Previous versions of this bill included several prescription drug provisions, including changes to:

- **Medicare drug price negotiation**
- **PBM reform**
- **Pharmacy reimbursement**

However, many of these **provisions were dropped from the final version of the bill**. For this reason, this presentation will primarily focus on executive actions on drug pricing.





# Most-Favored-Nation Drug Pricing





EO 14297 outlines actions federal agencies should take to **align US drug prices with the prices paid in other developed nations, or “most-favored-nation” pricing:**<sup>1</sup>

### Address “Freeloading” on US Innovation

*Commerce & US Trade Representative (USTR)*

- Take action to ensure other countries are not engaged in any “unreasonable or discriminatory” practice that “has the effect of **forcing American patients to pay for a disproportionate amount**” of global pharmaceutical R&D.
- **USTR issued an RFI** seeking input on the countries and policies/practices that raise concerns.<sup>2</sup>

### Enable Direct-to-Consumer Sales at MFN Price

*HHS*

- Facilitate **direct-to-consumer (DTC) purchasing programs** to make drugs available to patients at the most-favored nation (MFN) price.
- Unclear if such action would involve a government DTC program, or the expansion of **manufacturer DTC platforms** (e.g., LillyDirect, NovoCare).<sup>3,4</sup>
- The Trump administration has reportedly **met with large retailers** like Walmart and Amazon to facilitate this DTC effort.<sup>5</sup>



1. EO 14297. [Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients](#). May 2025.  
2. Office of the US Trade Representative. [USTR Seeks Comments Regarding Foreign Nations Freeloading on American-Financed Innovation](#). May 2025.  
3. Fuse Brown EC, Wouters OJ, Mehrotra A. [Partnerships between pharmaceutical and telehealth companies — increasing access or driving inappropriate prescribing?](#) *N Engl J Med*. 2025.  
4. Avalere Health Advisory. [MFN EO Raises A Range of Potential Options for DTC Implementation](#). June 2025.  
5. Cohrs Zhang R, Kang J. [Trump Officials Met With Walmart on Direct-to-Patient Drug Sales](#). *Bloomberg*. June 2025.



## Establish Most-Favored-Nation (MFN) Pricing

*HHS, CMS, and Other Relevant Agencies*

- Within 30 days, **communicate MFN price targets to manufacturers** that bring US prices in line with “comparably developed nations.”
- HHS announced that targets have been set, with the MFN target price being the **lowest price in an OECD country with a per capita GDP at least 60% of US GDP per capita.**<sup>1</sup>

If “significant progress” towards MFN pricing is not made, agencies may:<sup>2</sup>

- **Initiate rulemaking** to impose MFN pricing.
- **Facilitate importation** of low-cost drugs from other developed countries.
- Review and consider action on the **export of prescription drugs or precursor materials** that “may be fueling the global price discrimination.”
- Potentially **modify or revoke approvals for drugs** that may be “unsafe, ineffective, or improperly marketed.”
- Take any other action to “**address global freeloading and price discrimination.**”





**EO 14297 represents a revival of a policy first introduced during the first Trump administration**, which attempted to implement MFN pricing for drugs covered under Medicare Part B,<sup>1</sup> **with notable differences:**

<b>Broader Scope</b>	MFN prices may apply to a <b>broader selection</b> of drugs or segment of the market, not just those covered under Medicare Part B.
<b>Multiagency Involvement</b>	<b>Multiple departments/agencies beyond HHS</b> are tasked with implementing MFN prices, with a greater focus on trade policy. (e.g., <b>Customs and Board Protection issued a warning to manufacturers</b> to accurately report product import/export values.) <sup>2</sup>
<b>Voluntary First, Then Enforce</b>	Agencies are first expected to negotiate with manufacturers to <b>voluntarily implement MFN pricing</b> . Only if negotiations fail are agencies instructed to take further action. Conversations between manufacturers and HHS are reportedly ongoing. <sup>3</sup>
<b>Focus on DTC Access</b>	HHS indicated that the direct-to-consumer model is intended to be the key mechanism for MFN pricing, which may have implications for access to MFN prices using insurance. <sup>4</sup>



1. CMS. [Most Favored Nation Model for Medicare Part B Drugs and Biologicals Interim Final Rule with Comment Period](#). November 20, 2020.  
2. US Customs and Border Protection. [CBP Reminds Pharmaceutical Trade Community of Their Legal Obligations in Light of ‘Most-Favored-Nation’ Drug-Pricing Requirements](#). May 2025.  
3. Payne D, Chen E. Braced for details on Trump’s ‘most favored nation’ policy, pharma industry is still waiting. *STAT*. June 11, 2025.  
4. Payne D. [Trump administration demands pharma companies begin drug price negotiations, a day after key deadline](#). June 12, 2025



# Implications of MFN Pricing

There is savings potential if MFN pricing were successfully implemented, but the approach **is likely to face operational (and legal) challenges** that may limit savings.

## Examples:

- **Reference countries may keep negotiated prices confidential**, making it harder to reference. Prices may also not be available if a drug is not approved in the reference country.<sup>1</sup>
- Without a complementary price negotiation or health technology assessment process, MFN pricing may **make US prices more sensitive to pricing dynamics in other countries**, which can have unintended consequences.<sup>2</sup>





# Medicare Drug Price Negotiation





The **Medicare Drug Price Negotiation Program** is moving forward, including Maximum Fair Price (MFP) implementation and subsequent rounds of negotiations.

IPAY 2026	CMS has initiated pharmacy & manufacturer enrollment in the <b>Medicare Transaction Facilitator (MTF)</b> to enable MFP implementation. <sup>1</sup>
IPAY 2027	<b>Negotiations are ongoing</b> , with CMS having submitted its <b>initial MFP offers to manufacturers</b> by June 1. Manufacturers had until July 1 to accept the offer or propose a counteroffer. <sup>2</sup>
IPAY 2028	<p>CMS released <b>draft guidance for the IPAY2028 negotiations</b>, which address the inclusion of Part B drugs, the re-negotiation process, and MFP implementation in 2026-2028.<sup>3</sup> The agency has also submitted data collection forms for stakeholder feedback.<sup>4</sup></p> <p>The Trump administration has emphasized a desire to improve program transparency, prioritize high-cost drugs in the program, and minimize potential MFP innovation impacts.<sup>5</sup></p>

IPAY = Initial Price Applicability Year; MFP = Maximum Fair Price

1. CMS. [Medicare Transaction Facilitator General Resources](#). June 2025.  
2. CMS. [Fact Sheet: Medicare Drug Price Negotiation Program Final Guidance for 2027 and Manufacturer Effectuation of the MFP in 2026 and 2027](#). October 2024.  
3. CMS. [Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028](#). May 2025.  
4. 90 FR 27869. [Information Collection Request, CMS Form Number CMS-10849](#). July 2025.  
5. EO 14723. [Lowering Drug Prices by Once Again Putting Americans First](#). April 2025







# Changes to Drug Price Negotiation

The OBBB includes the ORPHAN Cures Act, which modifies the **orphan drug exclusion in price negotiation** beginning in IPAY 2028.<sup>1</sup>

<b>Previous Policy:</b>	Drugs with a <b>single rare indication</b> (“sole orphan” drugs) are exempt from price negotiation.	The 7- or 11-year waiting period for negotiation eligibility begins at the <b>approval of a drug’s first indication</b> .
<b>New Policy:</b>	Drugs with a <b>single rare indication <i>or multiple rare disease indications</i></b> (“multi-orphan” drugs) are exempt from price negotiation.	The 7- or 11-year waiting period for negotiation eligibility begins at the <b>approval of a drug’s first <i>non-rare</i> indication</b> .

CBO estimated that these changes would increase federal spending by **\$4.8 billion** through 2034.<sup>2</sup>

Given that the proportion of new drugs approved for rare indications has substantially increased in recent years, these changes could **decrease the number of drugs eligible for negotiation** or delay negotiation for these drugs, foregoing potential savings.<sup>3,4</sup>

1. H.R.1. *One Big Beautiful Bill Act, Section 71203*. 119<sup>th</sup> Congress. July 2025.  
2. CBO. *Estimated Budgetary Effects of H.R.1, the One Big Beautiful Bill Act*. May 2025.  
3. Vogel M, Zhao O, Feldman WB, Chandra A, Kesselheim AS, Rome BN. *Cost of Exempting Sole Orphan Drugs From Medicare Negotiation*. *JAMA Intern Med*. 2024;184(1):63.  
4. Mooney H, Kesselheim AS, Rome BN. *Congress Should Remove The Rare Disease Carve-Out From Medicare Drug Price Negotiation, Not Expand It*. *Health Affairs Forefront*. Published online June 27, 2025.





The Trump administration has also endorsed the EPIC Act to address the “pill penalty” / “biologics bonus” in price negotiation.<sup>1</sup>

Current Policy:	Qualifying <b>small molecule drugs</b> are eligible for price negotiation <b>7 years after FDA approval</b> , whereas <b>biologics</b> are eligible <b>11 years post-approval</b> .
Proposed Change:	Qualifying <b>small molecule drugs <i>and</i> biologics</b> are eligible for price negotiation <b>11 years after FDA approval</b> .

If this change were implemented, **>50% of drugs** selected for price negotiation in the 2026 & 2027 cycles **would not have qualified**.<sup>2</sup>

CBO reportedly estimated the EPIC Act’s cost as **\$10 billion** over a decade, while other researchers suggest a savings reduction of up to **\$36 billion** between 2026 and 2030.<sup>3,4</sup>

Evidence suggests that **biologics do not warrant differential treatment from small molecules**.<sup>5</sup>

Shifting all drugs to 11 years would mean that **MFPs would be in effect for a shorter period before generic competition**, reducing savings.<sup>6</sup>

1. H.R. 1492 / S.832. [Ensuring Pathways to Innovative Cures \(EPIC\) Act](#). 119<sup>th</sup> Congress. Introduced February 2025.  
2. Cubanski J, Neuman T. [The Effect of Delaying the Selection of Small Molecule Drugs for Medicare Drug Price Negotiation](#). KFF. April 2025.  
3. Knight V. [1 Big Number: EPIC Act Score](#). *Axios Pro*. April 2025.  
4. Verdant Research. [Negotiation Outcomes Calculator](#). West Health Mosaic. May 2025.  
5. Wouters OJ, Vogel M, Feldman WB, Beall RF, Kesselheim AS, Tu SS. [Differential Legal Protections for Biologics vs Small-Molecule Drugs in the US](#). *JAMA*. December 2024.  
6. Cai C, Kesselheim AS, Rome BN. [Costs of Extending the Small Molecule Exemption Period in Medicare Drug Price Negotiation](#). *Health Affairs Forefront*. May 2025.





# 340B Drug Discount Program





EO 14273 outlines anticipated federal agency action on the **340B Drug Discount Program**:<sup>1</sup>

Provision	Context
<b>Survey hospitals</b> to determine <b>hospital acquisition costs</b> for covered outpatient drugs in Medicare, and based on the findings, <b>propose adjustments to align Medicare payment</b> with acquisition costs.	Response to <b>previous Trump administration effort to reduce Medicare payment for 340B hospitals</b> that was blocked by the Supreme Court in 2022, in part because an acquisition cost survey had not been conducted. <sup>2,3</sup>
Condition grants to FQHCs on these 340B entities making <b>insulin and injectable epinephrine</b> available to low-income individuals <b>at or below the discounted 340B price</b> .  HRSA has since announced <b>updated award terms</b> for FQHCs to implement this provision. <sup>4</sup>	<b>Mirrors rule finalized in 2020 by the first Trump administration.</b> <sup>5</sup> The Biden administration later withdrew the rule, citing its unclear impact and the “excessive administrative burden” it would place on FQHCs. <sup>6</sup>

Meanwhile, 340B covered entities and manufacturers are awaiting further HHS guidance on the use of **a rebate model to provide 340B discounts**, amid ongoing litigation.<sup>7</sup>

1. EO 14273. [Lowering Drug Prices by Once Again Putting Americans First](#). April 2025

2. CMS. [CMS Issues Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System and Quality Reporting Programs Changes for 2018 \(CMS-1678-FC\)](#). November 2017.

3. Curfman G, Cole J. [The 340B Drug Discount Program Preserved After US Supreme Court Review—But Chevron Remains Vulnerable](#). *JAMA Health Forum*. 2022;3(9):e223185.

4. HRSA. [HRSA Announces Action to Lower Out-of-Pocket Costs for Life-Saving Medications at Health Centers Nationwide](#). June 2025.

5. 42 CFR Part 51c. [Implementation of Executive Order on Access to Affordable Life-Saving Medications](#). January 2021.

6. 42 CFR Part 51c. [Implementation of Executive Order on Access to Affordable Life-Saving Medications; Rescission of Regulation](#). October 2021.

7. Newton W. [HHS Submits 340B Rebate Guidance for Review, But Publication Timeline Remains Unclear](#). June 2025.





# FDA Actions





The Trump administration has also begun to outline its priorities in drug regulation under the FDA:

### Streamline Drug Importation

- EO14273 directs FDA to “streamline and improve” its process for states to submit **Section 804 Importation Programs (SIPs)**.<sup>1</sup>
- In response, the agency has proposed offering states the opportunity to **informally meet with FDA to get feedback on their SIP** before formal submission.<sup>2</sup>
- So far, **Florida is the only state that has obtained SIP approval**, and securing drug supply for importation remains a key challenge, even after SIP approval.<sup>3</sup>

### Support Domestic Drug Manufacturing

- EO 14221 directs FDA (and EPA) to review regulations and guidance related to domestic drug manufacturing and **eliminate any “duplicative or unnecessary” requirements**.
- FDA is instructed to **increase fees for and inspections of foreign drug manufacturing sites** and has shifted to **surprise inspections of these sites**.<sup>4</sup>
- These policy changes indicate an interest in prioritizing and streamlining agency review of domestic drug manufacturing sites.



1. FDA. [Importation Program Under Section 804 of the FD&C Act](#). Updated June 2025.  
2. FDA. [FDA takes steps to enhance state importation programs to help lower prescription drug prices](#). May 2025.  
3. FDA. [Letter of Authorization for Florida's Section 804 Importation Program](#). December 2024.  
4. FDA. [FDA Announces Expanded Use of Unannounced Inspections at Foreign Manufacturing Facilities](#). May 2025.



## Accelerating Drug Approvals

EO 14273 also directs FDA to issue a report with recommendations on how to:

- Accelerate the approval of **generics, biosimilars, combination products**, and **second-in-class brand-name drugs**
- Improve the process to reclassify drugs as **over-the-counter (OTC) products**.

Agency officials have announced plans to **accelerate drug review** timelines via:<sup>1</sup>

- The rollout of a **new AI tool** to facilitate the review process.<sup>2</sup>
- The launch of the **Commissioner's National Priority Voucher** pilot program, which grants 2-month review vouchers to companies “aligned with US national priorities.”<sup>3</sup>

Unclear how these stated priorities would intersect with **recent staff reductions at FDA**, which may have implications for review timelines.<sup>3</sup>

Important to note that the expedited approval of new drugs **does not guarantee they will be affordable or accessible to patients**.

**Vaccines appear to be a notable exception to this commitment to expedite FDA approval.**<sup>4,5</sup>



1. Makary MA, Prasad V. [Priorities for a new FDA](#). *JAMA*. Published online June 10, 2025.  
2. FDA. [FDA Launches Agency-Wide AI Tool to Optimize Performance for the American People](#). June 2025.  
3. Jewett C. [FDA Layoffs Could Raise Drug Costs and Erode Food Safety](#). *New York Times*. April 2025.  
4. FDA. [FDA to Issue New Commissioner's National Priority Vouchers to Companies Supporting U.S. National Interests](#). June 2025.  
5. Weber L, Roubein R, Sun LH, Johnson CY. [RFK Jr. will order placebo testing for new vaccines, alarming health experts](#). *Washington Post*. May 2025.  
6. HHS. [HHS Takes Bold Step to Restore Public Trust in Vaccines by Reconstituting ACIP](#). June 2025.



# Other Policy Developments







# PBMs & Pharmacies

Previous iterations of the OBBA would have modified **pharmacy & PBM reimbursement** in Medicaid and Medicare.<sup>1</sup> However, **none of these policies were included in the final bill.**

Medicaid
<ul style="list-style-type: none"><li>• Requiring retail, specialty, and mail-order pharmacy participation in the <b>National Average Drug Acquisition Cost (NADAC)</b> survey.</li><li>• Prohibiting <b>spread pricing</b>.</li><li>• Limiting pharmacy payment to <b>ingredient cost (NADAC) + a dispensing fee</b> for FFS Medicaid and MCOs.</li><li>• Limiting payments to PBMs to an <b>administrative fee</b></li><li>• Requiring PBMs <b>submit data to Medicaid programs and HHS</b> on all costs, payments, and fees for covered drugs.</li></ul>

Medicare
<ul style="list-style-type: none"><li>• Limiting payments to PBMs to a “<b>bona fide service fee</b>.”</li><li>• Requiring all manufacturer <b>rebates or discounts be passed through</b> to the Part D plan sponsor.</li><li>• Requiring PBMs to <b>annually submit data to HHS and Part D plan sponsors</b> on drug spending, and other aspects of PBM operations.</li></ul>

In the commercial market, EO 14273 directs Labor to propose ERISA **regulations to clarify PBMs’ disclosure obligations to self-funded plans** so employers can assess whether compensation provided to PBMs is “reasonable.”<sup>2</sup>



1. H.R.1. [One Big Beautiful Bill Act, Section 44124](#). 119th Congress. May 2025.  
2. Advisory Council on Employee Welfare and Pension Benefit Plans. [Report to the Secretary of Labor: PBM Compensation and Fee Disclosure](#). November 2014.



# Price Transparency

EO 14293 directs Treasury, Labor, and HHS to “rapidly implement and enforce” price transparency rules issued during the first Trump administration – the 2020 **“Transparency in Coverage” (TiC) final rule.**<sup>1,2</sup>

The TiC final rule requires health plans to **publicly disclose negotiated rates and historical net prices for covered drugs** furnished by in-network providers or pharmacies.

- Legal challenges ultimately deferred this reporting requirement.
- To date, the Departments have not issued finalized “form-and-manner” guidance operationalizing drug price reporting.

Treasury, Labor, and HHS/CMS **issued a joint RFI** seeking public input on the **prescription drug data** elements required under the TiC final rule.<sup>3,4</sup>



1. EO 14221. Making America Healthy Again by Empowering Patients with Clear, Accurate, and Actionable Healthcare Information. February 2025.  
2. EO 13877. Improving Price and Quality Transparency in American Healthcare To Put Patients First. June 2019.  
3. CMS. Departments of Labor, Health and Human Services, Treasury announce move to strengthen healthcare price transparency. May 2025.  
4. 90 FR 23303. Request for Information Regarding the Prescription Drug Machine-Readable File Requirement in the Transparency in Coverage Final Rule. June 2025.



# Medicaid Drug Spending

EO 14273 instructs HHS to provide the President with recommendations on how to **address other pharmaceutical issues in Medicaid**, including:

- (a) Ensuring manufacturers pay **accurate Medicaid drug rebates**
- (b) Promoting innovation in **Medicaid drug payment methods**
- (c) Better **aligning Medicaid payments** with drug value.
- (d) Supporting states in **managing drug spending**.

Trump administration previously pursued regulatory reforms to advance **value-based purchasing** in Medicaid and rules to remedy the **misclassification of certain drugs** in the Medicaid Drug Rebate Program.<sup>1,2</sup>

The administration also indicated a desire to build **on existing Medicaid prescription drug programs**, including the **Cell and Gene Therapy Access Model** for sickle cell disease.<sup>3,4</sup>



1. 89 FR 79020. [Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program](#). September 2024.  
2. 85 FR 87000. [Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review \(DUR\) and Supporting Value-Based Purchasing \(VBP\) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability \(TPL\) Requirements](#). December 2020.  
3. White House. [Fact Sheet: President Donald J. Trump Announces Actions to Lower Prescription Drug Prices](#). April 2025.  
4. CMS. [Cell and Gene Therapy \(CGT\) Access Model](#). January 2025.



# Medicare Payment & Premiums

EO 14273 instructs HHS to provide a rulemaking plan to test **payment models that improve Medicare's ability to obtain "better value" for covered drugs**

- **CMS Innovation Center (CMMI)** has announced its 2025 strategy, including a focus on "[driving] better spending and outcomes for prescription drugs."<sup>2</sup>

The EO also directs HHS to ensure that Medicare payment for clinician-administered drugs is **"site neutral."**<sup>3</sup>

The Trump administration has also requested recommendations from HHS on how to **stabilize Part D premiums**, building on actions taken by Biden administration.<sup>4</sup>





# Other Policies

Other pharmaceutical policy areas in which recent action has been proposed or taken by the Trump administration or Congress:

Pharmaceutical Tariffs	The Department of Commerce continues to conduct its <b>Section 232 investigation</b> into pharmaceutical products—a precursor to tariffs. <sup>1</sup> This investigation could reportedly conclude in time to impose pharmaceutical tariffs later this month. <sup>2</sup>
R&D Cost Expensing	The OBBB permits companies to <b>immediately deduct domestic R&amp;D costs for tax purposes</b> , ending a previous requirement to amortize these expenditures over a 5-year period. <sup>3</sup>
Addressing Anticompetitive Behavior	FTC and DOJ are conducting a series of <b>listening sessions</b> focused on <b>generic/biosimilar competition, formulary practices, and other pricing issues</b> . <sup>4</sup>  The FTC has also reiterated its challenges to <b>improperly-listed patents in the FDA Orange Book</b> , continuing a Biden-era effort. <sup>5</sup>

1. Industry and Security Bureau. [Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients](#). 90 FR 15951. April 16, 2025.

2. Swanson A. [Threat of More Tariffs Hangs Over Countries Negotiating Trade Deals](#). *New York Times*. June 2025.

3. H.R.1. [One Big Beautiful Bill Act, Section 70302](#). 119<sup>th</sup> Congress. July 2025.

4. FTC. [FTC and DOJ to Host Listening Sessions on Lowering Americans' Drug Prices Through Competition](#). June 2025.

5. FTC. [FTC Renews Challenge of More Than 200 Improper Patent Listings](#). May 2025.





# Summary

Since taking office in January, the Trump administration has announced a series of policies and initiatives aimed at addressing prescription drug affordability, manufacturing, and regulation.


These efforts have been paired with Congressional proposals to reform some aspects of the pharmaceutical supply chain and reimbursement system.

However, many of these policy proposals lack sufficient detail to fully assess the feasibility of implementation and their potential impact on the US health care system and patients.



# Questions?

**Program On Regulation, Therapeutics, And Law (PORTAL)**

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