

TxSCO Update

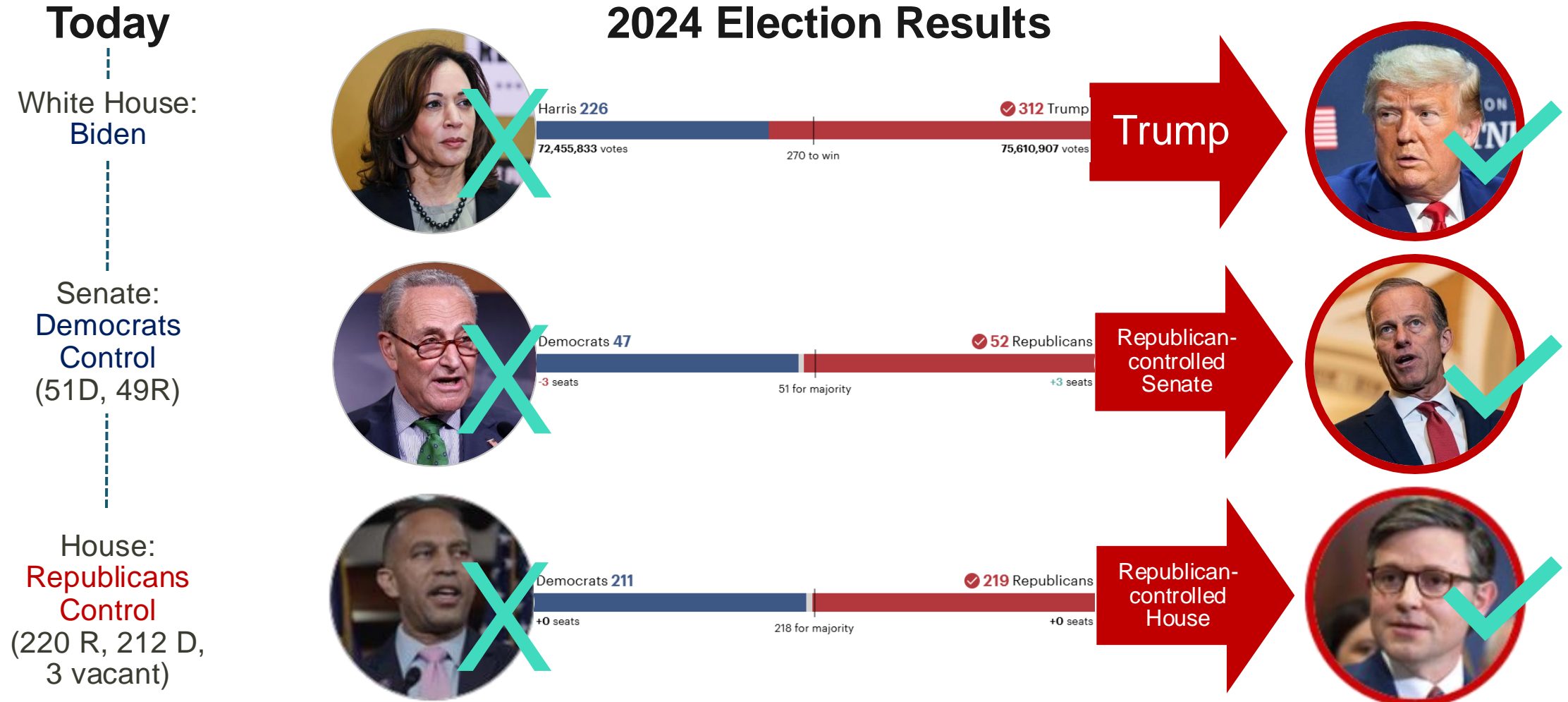
November 14, 2024

ADVI & HillCo



Federal Updates

2024 Election: Trump White House, Republican Senate & Republican House



2024 Election: Trump White House, Republican Senate & Republican House

President

226 Harris/Walz Trump/Vance 312



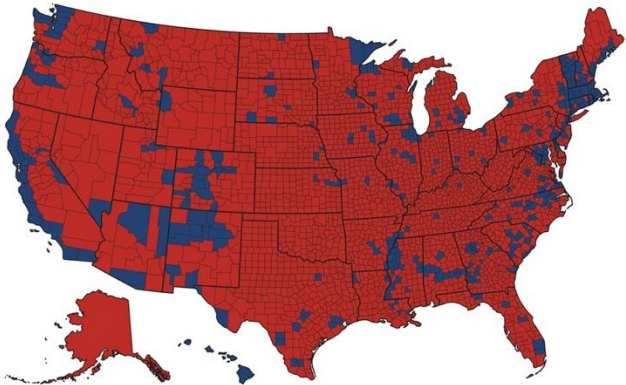
Senate

47*(-4) Democrats Republicans 53(+4)



House

210(-1) Democrats Republicans 219(+1)



Legislative & Regulatory Scenarios

	Trump / Senate - R / House - R: Legislative Actions	Trump Administration: Regulatory Actions
IRA Govt “Negotiation”	<ul style="list-style-type: none"> Attempt full repeal of negotiation policy Orphan CURES “Pill Penalty” fix: pushback negotiation eligibility (7 → 11yr) Part B drug ASP fix Establish MFP Floor New indications: restart/delay clock Medicaid Best Price: MFP no longer apply 	<ul style="list-style-type: none"> Award MFPs close to ceiling Add International Reference Pricing-like considerations for IPAY 2028*
Medicare	<ul style="list-style-type: none"> Providers: <ul style="list-style-type: none"> “Doc Fix” to address provider reimbursement Site Neutral payment reforms Medicare Advantage: Project 2025 calls for – <ul style="list-style-type: none"> Making MA the default enrollment option for seniors Reconfiguring the current risk adjustment model Replacing the complex formula-based payment model with a competitive bidding model 	<ul style="list-style-type: none"> CMMI <ul style="list-style-type: none"> Pursue alternatives to ASP+6% reimbursement (e.g., CAP 2.0, Theo Merkel’s proposal tying coverage/reimbursement to MA plan contracting) Revive International Reference Pricing proposed models* Part D 6 Protected Classes: Reduce or eliminate coverage rules (e.g., Trump’s past Part D Payment Modernization Model) Adapt successful models for other therapeutic areas (e.g., Part D Senior Savings Model) Given recent scrutiny of CMMI’s lack of savings, either push mandatory models or design models to guarantee savings are achieved
Medicaid	<ul style="list-style-type: none"> Work requirements Consider block grants 	<ul style="list-style-type: none"> Approve State Medicaid requests for closed formularies, work requirements, block grant waivers
Commercial	<ul style="list-style-type: none"> ACA Premium Tax Credits <ul style="list-style-type: none"> Allow enhanced generosity to expire New oversight of income attestation US manufacturing incentives (e.g., BIOSECURE Act) 	<ul style="list-style-type: none"> Accumulator/Maximizers: revisit definition of cost-sharing (per court ruling) Approve State Importation Plans Enforce recommendations from FTC investigation of PBMs Pursue “Foreign Freeloading” stipulations in trade deals
340B	<ul style="list-style-type: none"> Transparency and oversight 	<ul style="list-style-type: none"> Part B drug reimbursement <ul style="list-style-type: none"> Revive past attempts to reduce Part B drug reimbursement for 340B hospitals (e.g., ASP – 22.5%) HRSA: allow Contract Pharmacy rebate model
PBM	<ul style="list-style-type: none"> Transparency and “delinking” Potential for more: rebate pass-through, spread pricing prohibitions 	<ul style="list-style-type: none"> Attempt policy similar to OIG Rebate Rule
“MAHA”	<ul style="list-style-type: none"> Make America Healthy Again (MAHA) <ul style="list-style-type: none"> RFK, Jr. to lead investigation into the “the decades-long increase in chronic health problems, including autoimmune disorders, autism, obesity, infertility and many more.” 	

*International Reference Pricing (IRP) is not a current Trump priority, but given Trump’s focus on IRP in the past, this topic could reappear in the future

Trump 2.0: Foreign Freeloading, PBMs & “MAHA”



Government Price Controls

- **International Reference Pricing:** revive the MFN?
 - Trump [campaign video](#) from June 2023: “On Day One of my new term, I will sign an executive order to end this global freeloading on American consumers for once and for all... Under my policy, the United States government will tell Big Pharma that we will only pay the best price they offer to foreign nations, who have been taking advantage of us for so long – the United States is tired of getting ripped off.”
 - [Oct. 2, 2024](#): Spokesperson said Trump won't pursue MFN and the June 2023 video was removed from the campaign website. **Regardless, IRP has been such a focus for Trump that the threat of new CMMI proposals remains.**
- **IRA Government Negotiation implementation:** rebrand or phone it in?
 - Even if Republicans gain control of the WH and Congress, negotiation is unlikely to be repealed given the need for ~\$200B in offsets. Unclear how a Trump-led CMS would implement the policy. Could rebrand it as a Trump initiative and incorporate IRP elements or implement without fanfare and set MFPs at/near the ceiling.

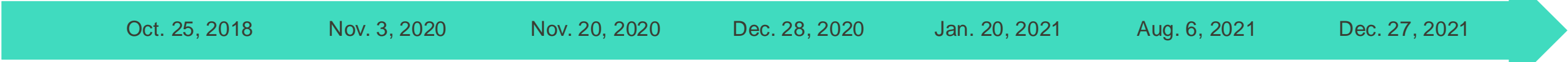
PBMs, 340B, Importation & Part B Drugs

- **PBMs:** Democrats repealed Trump's OIG Rebate Rule in the IRA, making PBM reform a key piece of unfinished business. Trump could reignite his focus on “middlemen” through CMS, OIG or FTC action.
- **340B:** In 2018, **CMS reduced Part B drug reimbursement for 340B covered entities to ASP minus 22.5%.** In 2022, the Supreme Court held the cuts were unlawful due to CMS not first conducting a survey of hospitals' acquisition costs. In a second term, Trump could revisit such a policy. Additionally, a Trump-led HRSA may be open to a Contract Pharmacy rebate model that was attempted by J&J.
- **Importation:** In 2020, the FDA finalized a new pathway to allow states to import prescription drugs from Canada. To date, several states have submitted plans but only Florida's has been approved. A second Trump administration could accelerate the pace of state plan approvals and implementation.
- **Part B Drugs:** In 2018, CMMI proposed, but did not finalize, the “International Pricing Index” (IPI) Model that would have imposed international reference pricing and eliminated buy-and-bill by allowing private-sector vendors to negotiate prices for drugs and take title to drugs (i.e., “CAP 2.0”). A Trump 2.0 CMMI might again pursue alternatives to ASP+6% reimbursement in a demo (e.g., CAP 2.0 and/or Theo Merkel's proposal tying coverage/reimbursement to MA plan contracting).
- **Cell & Gene Therapy:**
 - CAR-T: CMS [announced](#) a Medicaid VBA demo for KYMRIA in 2017, but [canceled](#) it months after claims that Novartis received “favorable treatment.”
 - CMMI Cell & Gene Therapy Access Model: no indication of Trump stopping this model; expected to continue.

Coverage, Transparency & “MAHA”

- **ACA:** Trump said he was not running on terminating the ACA and would rather make it “much better and far less money.”
- **Medicare:** Trump would “always protect Medicare, Social Security, and patients with pre-existing conditions” including no changes to the retirement age (no specific policies proposed), but also proposed increased Medicare premiums for higher-income beneficiaries.
- **Medicaid:** Trump administration previously approved waivers that included work requirements as a condition of Medicaid eligibility, premiums, and other eligibility restrictions.
- **Transparency:** Issued an executive order on price transparency, leading to a rule requiring hospitals to post negotiated charges for their services online using authority from the ACA.
- **Make America Healthy Again (MAHA):** Trump said RFK, Jr. could “do whatever [he] wants” on healthcare and would ask Kennedy to work on a panel to investigate “the decades-long increase in chronic health problems, including autoimmune disorders, autism, obesity, infertility and many more.”

Trump 2.0: Recap of Past International Reference Pricing (IRP) Attempts



Oct. 25, 2018

- [International Pricing Index \(IPI\) ANPRM](#) released



IPI targeted 27 Part B drugs, would have based reimbursement on 126% of int'l prices and moved to a vendor-led system in lieu of buy-and-bill

Nov. 3, 2020

- *Election: Trump loses*

Nov. 20, 2020

- [Most Favored Nation \(MFN\) Interim Final Rule](#) released



MFN targeted 50 Part B drugs and would have based reimbursement on the lowest per capita GDP-adjusted price of any non-U.S. member country of the OECD

Dec. 28, 2020

- *BIO v. Azar*: Court granted a [preliminary injunction](#) – blocking the **MFN** from implementation (unless/until traditional rulemaking pursued)

Jan. 20, 2021

- *Biden sworn in*

Aug. 6, 2021

- CMS proposed to formally rescind the **MFN** Model

Dec. 27, 2021

- CMS rescinded the **MFN** Model in a final rule

How it started

- The threat of IRP began in May 2018 with the Trump administration's [Blueprint to Lower Drug Prices](#), that was soon followed by the release of the IPI proposal as Trump sought to address "foreign [freeloading](#)," claiming manufacturers were "[giving bargain basement prices to other countries](#)"
- Democrats continued the IRP focus with introduction of [H.R. 3](#) in 2019 (limiting prices to 120% of ex-U.S. prices) and reintroduction in 2021 (limiting prices to the lowest average ex-US price across 6 countries) and [Pres. Biden's campaign platform](#)
- Numerous reports released, including:
 - [ASPE](#) (Oct. 2018): U.S. pays 1.8x more than other countries for Part B drugs
 - [ASPE](#) (Nov. 2020): U.S. pays 2.1x more than high income OECD countries for Part B drugs
 - [GAO](#) (March 2021): U.S. pharmacy benefit drug prices are 2 – 4x higher than other countries
 - [RAND](#) (Jan. 2021): U.S. drug net prices are 2.3x higher than other countries
 - [ASPE](#) (July 2022): U.S. prices were 256% of those in 32 comparison countries
 - [RAND](#) (Feb. 2024): U.S. prices were 278% of other countries' prices

"Foreign Freeloading": Unfinished Business for Trump?

- [DonaldJTrump.com](#), Better Health Care Choices at Lower Costs (2024 campaign site):
 - "President Trump lowered drug prices for the first time in over 50 years and finalized the Most Favored Nation Rule to ensure that pharmaceutical companies offer the same discounts to the United States as they do to other nations."
 - "He will stop all COVID mandates and restore medical freedom, end surprise medical billing, increase fairness through price transparency, and further reduce the cost of prescription drugs and health insurance premiums."
- [Agenda47](#), Protecting Americans by Taking on Big Pharma and Ending Global Freeloading (Trump video 6/23/2023):
 - "On Day One of my new term, I will sign an executive order to end this global freeloading on American consumers for once and for all... Under my policy, the United States government will tell Big Pharma that we will only pay the best price they offer to foreign nations, who have been taking advantage of us for so long – the United States is tired of getting ripped off."
- [Oct. 2, 2024](#): Spokesperson said Trump won't pursue MFN and the [June 23, 2023 video was removed from the campaign site. Regardless, IRP has been such a focus for Trump that the threat of new proposals remains.](#)



Trump 2.0: “Make America Healthy Again” (MAHA)



RFK, Jr.:

Do “whatever you want” on Healthcare

10/26/2024: Joe Rogan Experience Podcast

- JOE ROGAN: Do you have anyone that is pressuring you to not work with [RFK, Jr.]?
- DONALD TRUMP: Yes.
- JOE ROGAN: Yes. I would imagine. Because financially, he could put a dent-
- DONALD TRUMP: I would say that. I think in many ways they’ve [pharmaceutical industry] done a good job. In many ways they’ve done a bad job. **But I would say that the big pharma wasn’t thrilled when they heard that.** I’ve actually always gotten along very well with him. I’ve known him a long time.
- JOE ROGAN: Are you completely committed to have him be a part of your administration?
- DONALD TRUMP: Oh, I am. But the only thing I want to be a little careful about with him is the environmental, because he doesn’t like oil. I love oil and gas. So I’m going to sort of keep him out of it. I said, **“Focus on health. You can do whatever you want, but I’ve got to be a little bit careful with the liquid gold.”**



10/27/2024: Madison Square Garden Rally

- Trump said “I’m going to let him [RFK, Jr.] go wild on health. I’m going to let him go wild on the food. **I’m going to let him go wild on the medicines.**”

10/28/2024: Virtual event, video on X

- Kennedy [claimed](#) Trump “promised” he could have **“control” of public health agencies**, including HHS, FDA, CDC, NIH and USDA.

Vaccines:

Defends industry for “some amazing things”

10/26/2024: Joe Rogan Experience Podcast

- JOE ROGAN: Some pharmaceutical drugs that have been prescribed that have negative consequences that these people have been profiting off of, and then you have a guy like RFK Jr. who spends an enormous amount of time highlighting those things, you could see how they’ve been very reluctant to have you support him.
- DONALD TRUMP: I would say that’s an understatement.
- JOE ROGAN: Yeah. So what do you do to stop that from getting in the way?
- DONALD TRUMP: Well, look, **they’ve come up with some amazing things.** I mean, I don’t know how you feel. I know you’re against certain vaccines, but like the polio vaccine, **people had polio. It was like a disaster. And they came up, Dr. Salk, and he came up with a vaccine, and there’s no polio.** Now, very interesting, there hasn’t been polio, but now in the Gaza Strip, can you believe that? There’s been a big strain of polio coming out in the Gaza Strip.



Chronic Diseases:

RFK, Jr. to lead a panel

8/23/2024: Arizona Rally

- Trump said he would ask Kennedy to work on a panel to **investigate “the decades-long increase in chronic health problems, including autoimmune disorders, autism, obesity, infertility and many more.”**



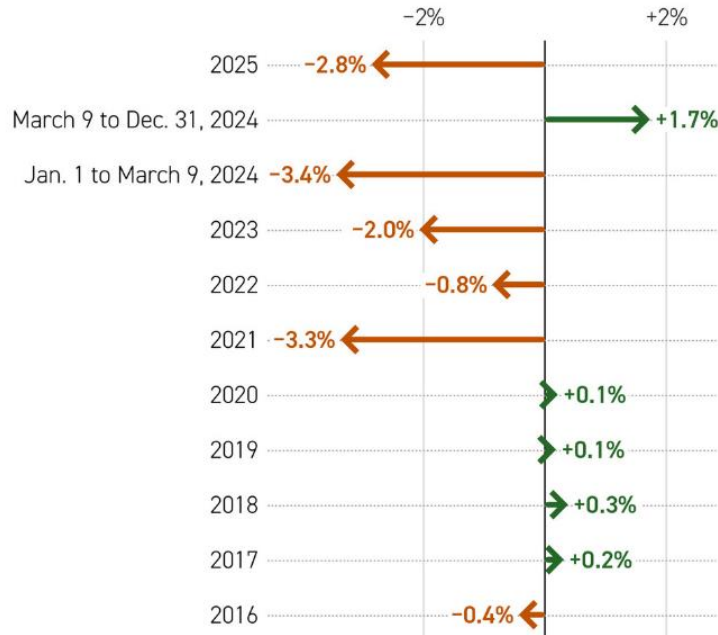
Bill Introduced to Increase Medicare Physician Payments by 4.73% in 2025

Oct. 29, 2024: Bipartisan representatives introduced HR 10073 to increase Medicare physician payments by 4.73% for 2025.

Where things stand today:

CMS proposes fifth physician pay decrease since 2021

Percentage change in physician fee schedule conversion factor from previous rate



Source: American Medical Association, Centers for Medicare and Medicaid Services
Madi Alexander/POLITICO

HR 10073, Medicare Patient Access and Practice Stabilization Act

- Increase support for physicians and other practitioners adjusting to Medicare payment changes
- Include a partial **inflation adjustment to help offset rising medical practice costs, equal to 50% of the Medicare Economic Index (MEI)**
- CMS expects the MEI to rise by 3.6% this year



Representative
Greg Murphy
(R-NC), M.D.

“America’s physicians are at a breaking point and access to high-quality, affordable care is at risk for millions of Medicare patients... Medical inflation is much higher and the cost of seeing patients continues to rise. Unfortunately, reimbursements continue to decline, putting immense pressure on doctors to retire, close their practices, forgo seeing new Medicare patients, or seek a less efficient employment position. **This bipartisan legislation would stop yet another year of reimbursement cuts, give them a slight inflationary adjustment, and protect Medicare for physicians and patients alike.**”

Sources: Congressman Murphy Press Release (10/29/24, [link](#)); IHP (10/29/24, [link](#)); Bill Text (10/22/24, [link](#))

Potential “Lame-Duck” Congressional Healthcare Priorities

Overview

- Congress must pass another continuing resolution (CR) (or appropriations package) by Dec. 20, 2024, to avoid a government shutdown
- Several healthcare related policies have been raised as potential priorities to include in year-end legislation, however, there are other non-healthcare related bills that may be prioritized (e.g., disaster relief)
- Additionally, given Republican control of the White House and Congress next session, there may be less Republican interest in advancing notable bipartisan healthcare reforms in the 2024 lame duck

Likely Priority Healthcare Legislation

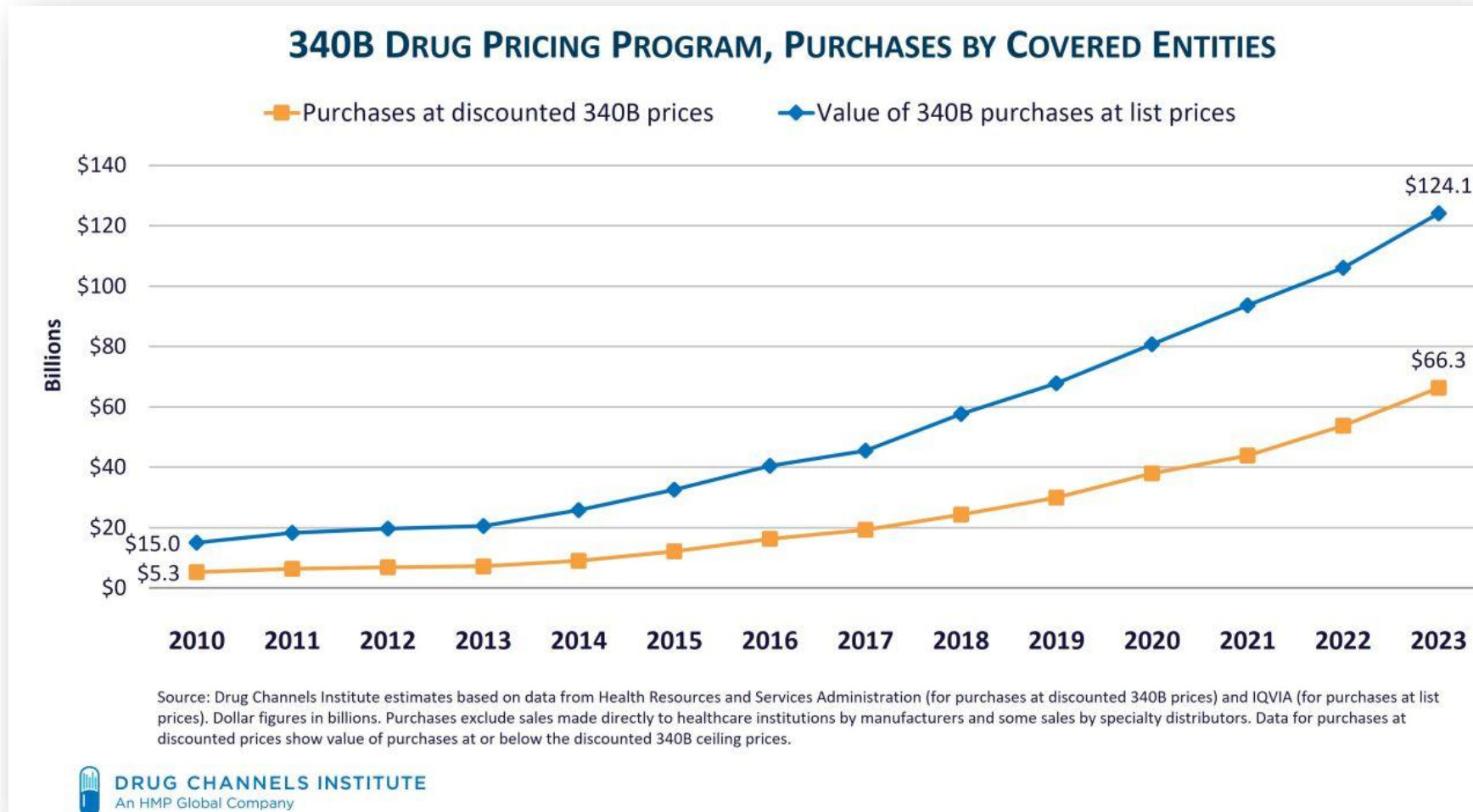
- Offset the looming [2.8% Medicare PFS reimbursement](#) cut for providers
- Extend [COVID-19 flexibilities for telehealth](#) and hospital care at home
- Continue extenders from previous CR, including:
 - Extend expiring funding for [community health centers](#)
 - Delay [Medicaid DSH payment reductions](#)

Other Healthcare Legislation

- Moderate likelihood to be included in year-end legislation
 - Extension of the [Rare Pediatric Disease Priority Review Voucher \(PRV\) program](#)
 - The PRV program has bipartisan support and was included in a bill the House passed in Sept. 2024
 - [BIOSECURE Act \(H.R.7085/S.3558\)](#)
 - The House passed the BIOSECURE Act in Sept. 2024, but it has not moved in the Senate
- Unlikely to be included in year-end legislation
 - Substantial [PBM reform](#) (if anything, transparency focused provisions are more likely to be advanced, while “delinking” and spread pricing focused provisions are not)
 - [340B reform](#) (e.g., SUSTAIN 340B Act, 340B PATIENTS Act)
 - [Site-neutral](#) payment policies for hospital outpatient departments
 - Extension of enhanced generosity for ACA Exchange [premium subsidies](#) (aka, Advanced Premium Tax Credits (APTCs))

HRSA: Discounted Purchases Under 340B Hit \$66B in 2023, +24% over 2022

On October 18, 2024, HRSA released its 2023 340B Covered Entity purchases data showing a 24% increase in 340B discounted purchases from 2022 to 2023.



- The **gross-to-net difference** between list prices and discounted 340B purchases also **grew to \$57.8B (+\$5.5B)**
- 340B purchases are now almost 40% larger than Medicaid's prescription drug purchases

Source: HRSA (10/18/24, [link](#)); Adam Fein (10/18/24, [link](#)); Stat+ (10/18/24, [link](#))

HRSA: Discounted Purchases Under 340B Hit \$66B in 2023, +24% over 2022

Discounted purchases under 340B has nearly doubled since 2019, with DSH accounting for 78% (\$51B) of all spending in 2023

Entity Type	2023 Total Purchases
Disproportionate Share Hospitals	\$51,886,954,092
Health Center Programs	\$3,604,902,123
Children's Hospitals	\$2,068,940,096
Rural Referral Centers	\$1,466,883,786
Ryan White HIV/AIDS Program Part A	\$1,509,011,588
Sexually Transmitted Disease Clinics	\$1,656,919,741
Critical Access Hospitals	\$955,896,370
Ryan White HIV/AIDS Program Part C	\$706,922,298
Sole Community Hospitals	\$554,770,578
Free-standing Cancer Centers	\$506,321,424
Ryan White HIV/AIDS Program Part B	\$303,659,916
Ryan White Part B AIDS Drug Assistance Program (ADAP) Direct Purchase Option	\$242,321,523
Comprehensive Hemophilia Treatment Centers	\$340,953,762
Federally Qualified Health Center Look-Alike Program	\$344,997,724
Family Planning Clinics	\$37,879,948
Ryan White HIV/AIDS Program Part D	\$35,126,473
Tribal Contract/Compact with IHS (P.L. 93-638)	\$58,967,807
Tuberculosis Clinics	\$7,859,813
Urban Indian Hospitals	\$2,545,040
Black Lung Clinics	\$843,769
Ryan White Part B ADAP Rebate Option	\$42,455
Native Hawaiian Health Care Programs	\$62,307
Total	\$66,292,782,635

The Top 10 drugs in terms of 340B purchases represented approximately 1/3 of the total spending in the 340B Program

Brand Name	Primary Indications	2023 Total 340B Sales
Keytruda	Oncology	\$6,905,377,755
Biktarvy	HIV	\$3,577,083,273
Opdivo	Oncology	\$1,953,824,181
Darzalex Faspro	Oncology	\$1,891,559,523
Ocrevus	Oncology	\$1,850,213,455
Trikafta	Cystic Fibrosis	\$1,817,226,143
Humira (CF) Pen	Immunology	\$998,809,804
Descovy	HIV	\$969,510,516
Entyvio	Immunology	\$949,744,300
Durvalumab	Oncology	\$889,594,527

HRSA: Discounted Purchases Under 340B Hit \$66B in 2023, +24% over 2022

Brand Name	Company	2023 Total 340B Sales	2023 US Sales	340B as a % of US Sales
Keytruda	Merck	\$6,905,377,755	\$ 15,114,000,000.00	45.7%
Biktarvy	Gilead	\$3,577,083,273	\$ 9,692,000,000.00	36.9%
Opdivo	BMS	\$1,953,824,181	\$ 5,283,000,000.00	37.0%
Darzalex Faspro	JNJ	\$1,891,559,523	\$ 5,277,000,000.00	35.8%
Ocrevus *	Roche	\$1,850,213,455	\$ 5,414,591,349.00	34.2%
Trikafta **	Vertex	\$1,817,226,143	\$ 5,473,000,000.00	33.2%
Humira (CF) Per	AbbVie	\$998,809,804	\$ 2,740,000,000.00	36.5%
Descovy	Gilead	\$969,510,516	\$ 1,771,000,000.00	54.7%
Entyvio *	Takeda	\$949,744,300	\$ 3,652,476,261.00	26.0%
Imfinzi	AstraZeneca	\$889,594,527	\$ 2,317,000,000.00	38.4%
* Roche and Takeda do not report revenues in USD. Sales converted to USD as of the 10/18/24				
** Vertex doesn't break out U.S. vs OUS revenue on a product basis. U.S. sales estimated				

State Updates



2024 Texas General Election Results

- The general election last week yielded expected results of the Republicans maintaining control of both chamber of the state Legislature, as well as the US Senate, as Ted Cruz handily won the challenge against Collin Allred.
- The Texas House gained two Republicans, and the Senate gained one.
- The Republican election success is setting up a significant Speaker's race, as the current Speaker is facing multiple challenges and even had President Trump endorse his opponent in the primary race this Spring.
- The House Republicans are scheduled to meet in early December and plan to vote on and select the candidate that will be nominated for Speaker on January 14th, the opening day of the 89th Legislative Session.
- The House Rules will be debated and voted on the following day, and significant changes could occur including the prohibition of Democratic chairs.

Bill Filing

- Bill filing started in earnest on November 12th, with 1,261 bills filed by House members, and 324 bills filed by Senators.
- Some highlights from the first day of bill filing include:
 - HB 198 by Bumgarner (D) – would require political subdivisions that employ firefighters to offer a no cost occupational cancer screening in the 5th year of the firefighter’s employment, and once every 3 years following. The screening would test for colorectal cancer, prostate cancer, lung cancer, and brain cancer.
 - HB 233 by Gervin-Hawkins (D) – would require a health benefit plan to provide coverage for a hair prosthesis for an enrollee who is undergoing or has undergone medical treatment for breast cancer.
 - SB 315 by Kolkhorst (R) – would establish that an individual has an exclusive property right in the individual’s unique DNA.

Legislative Dates of Interest

- November 12, 2024 – First day legislators and legislators-elect may file bills for the 89th Legislature.
- January 14, 2025 – 89th Legislature convenes at noon.
- March 14, 2025 – 60-day deadline for bill filing.
- June 2, 2025 – Sine die – last of day of 89th Regular Session.

ADVI

*Thank
You*



APPENDIX

Global Cancer Burden Study

On November 5, 2024, researchers from the University of Queensland, Australia, released a study that measured the global burden of 36 cancers in 2022 and projected the future trends of these diseases by 2050.

Key Takeaways

- Cancer cases are projected to increase by nearly 77% from 2022 to 2050 and reach 35.3 million cases worldwide
- Cancer cases and deaths are projected to nearly triple in low-Human Development Index (HDI) countries by 2050, compared to a moderate increase in high-HDI countries
- The increases, respectively, are 142.1% vs 41.7% for cancer cases and 146.1% vs 56.8% for cancer deaths

Statistics

- There were 1,977,459 cancer survivors in the United States in 2022
- The prevalence rate of cancer in the United States was 590.6
- The US is expected to experience 60.9% more cancer deaths in 2050 than 2022
- US cancer case rates are expected to increase 47.5% in 2050 as compared to 2022
- The top five cancers globally, by prevalence, are projected to be breast, prostate, colorectum, lung, and non-melanoma skin cancer in 2050.

Age Standardized Incidence Rates, 2022

