



ADVI

TxSCO Update

Nov. 10, 2022



Overview: Notable Updates

Federal

- Midterm Election
- PFS Final Rule
- OPPS Final Rule
- Executive Order: CMMI demo on drug pricing (potential impact on provider reimbursement)
- IRA & EOM: the latest
- Appendix: additional Midterm Election slides

State

- Texas Election Recap
- Upcoming Legislative Milestones

Federal Update

Where Things Stand

The current balance of power in the Senate

The number of seats each party will control based on the election results as of 4:20 a.m. Eastern

■ DEMOCRATIC SEAT ■ DEMOCRATIC WIN ■ UNCALLED ■ REPUBLICAN WIN
■ REPUBLICAN SEAT

Current balance of power



2022 midterm results



If the Senate is split 50-50, Democrats maintain majority control because Vice President Kamala Harris has the tiebreaking vote. Independent Sens. Bernie Sanders and Angus King are included as Democrats because they caucus with that party.

FiveThirtyEight

SOURCE: ABC NEWS

The current balance of power in the House

The number of seats each party will control based on the election results as of 4:21 a.m. Eastern

■ DEMOCRATIC WIN ■ UNCALLED ■ REPUBLICAN WIN

Current balance of power



2022 midterm results



According to ABC News estimates.

FiveThirtyEight

Mid Term Election Outcome Dynamics

As of Wednesday morning November 9, neither party has achieved a majority in either chamber.

Republicans are safely projected to win the House however with what margins are still unknown based on dozens of uncalled races. Democrats won some open competitive seats that typically go for the party in the Republicans' position in the midterm.

Republicans only needed to net one seat in the Senate to gain the majority. Senate seats in Arizona, Georgia and Nevada are still uncalled. Democrats need to hold on to two of those three seats to retain their majority.

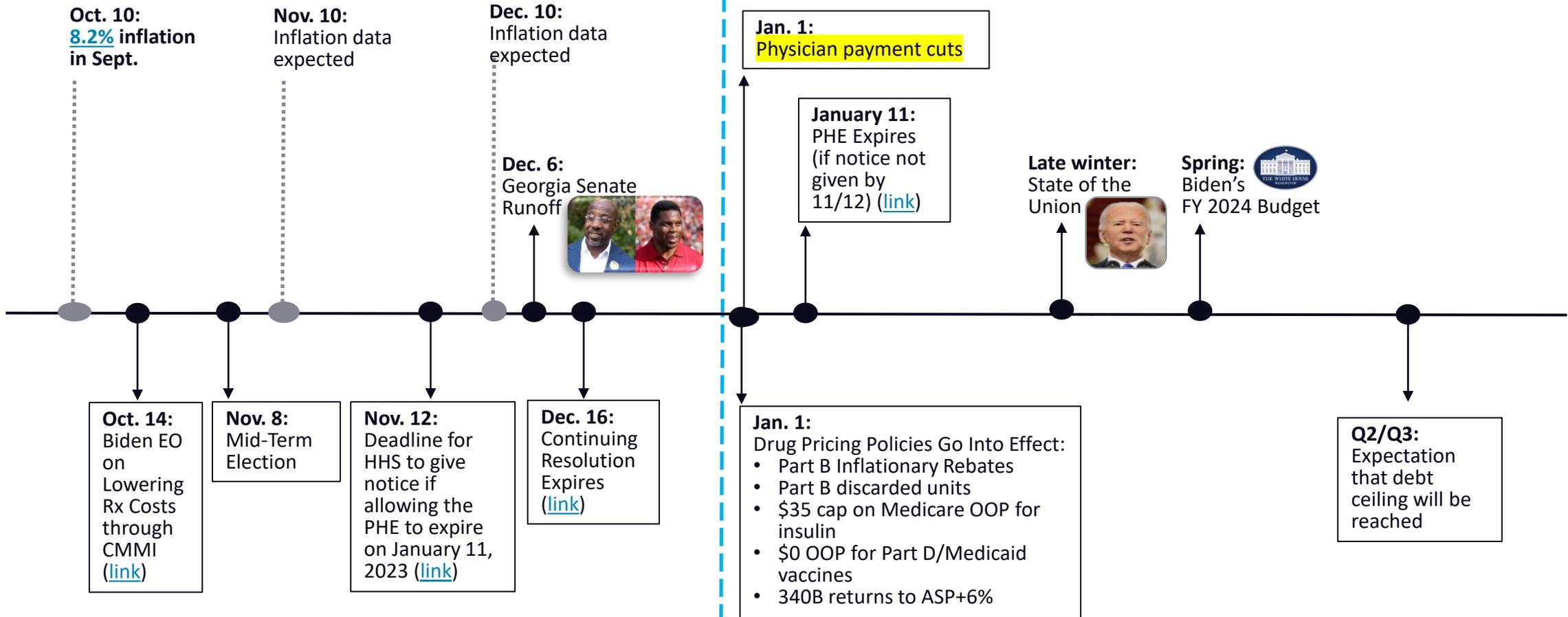
Unless the same party wins both the Arizona and Nevada races, the Senate majority won't be known until the outcome of the Georgia runoff between Sen. Raphael Warnock (D) and Herschel Walker (R), scheduled for December 6, 2022.*

The full results of the election are still unknown and Democrats will see losses compared to the status quo. However, given the combination that the president's party typically does poorly in midterm elections and President Biden's mediocre approval rating, the results did not end up with the "red wave" that some were predicting.

Political Timeline



2023



PFS Final Rule for CY 2023

November 1, 2022. CMS released the CY 2023 Physician Fee Schedule (PFS) Final Rule ([link](#)).

Conversion Factor

- The final conversion factor is \$33.06, a 4.5% decrease from \$34.61 in CY 2022 (see Table 148)
 - Hematology/oncology**: -1% **Radiation oncology**: -1%

Telehealth

- Finalized the addition of:
 - 54 services to the Telehealth Services List on a Category III basis (Table 12 of the final rule)
 - 5 services to the Telehealth Services List on a Category I basis (Table 13 of the final rule)
- Finalized its proposal to extend the availability of telehealth services available during the PHE, but included on a Category I, II, or III basis for 151 days after the end of the PHE to align with provisions signed into law in the Consolidated Appropriations Act, 2022.

E/M Services

- Finalized the adoption of changes to the E/M code set proposed by the American Medical Association CPT Editorial Panel except for certain prolonged service codes effective January 1, 2023
- For prolonged E/M services, finalized the proposal to create Medicare specific HCPCS codes G0316, G0317, G0318 for inpatient and observation visits, nursing facility, and home or residence visits, respectively

QPP

- Will accept 5 new MVPs for reporting including: Advancing Cancer Care
- Finalized proposal to allow individual clinicians, single specialty groups, multispecialty groups, subgroups, and APM Entities to report MVPs. Beginning in 2026, multispecialty groups will no longer be eligible to report MVPs
- MIPS weights for 2023: Quality (30%), Cost (30%), Promoting Interoperability (25%), Improvement Activities (15%)

Colorectal Cancer Screening

- Finalized proposal to reduce the minimum age for CRC screening tests from 50 to 45 years of age for certain Medicare covered CRC screening tests
- A screening colonoscopy will continue to not have a minimum age limitation
- Finalized proposal to expand the definition of CRC screening tests to include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based CRC screening test returns a positive result.
 - No beneficiary cost sharing for the stool-based test or the follow-on colonoscopy screening tests

Radiation therapy services mentioned:

(43) Radiation Oncology Model

On August 29, 2022, CMS finalized delaying the current start date of the Radiation Oncology Model (ROM) to a date to be determined through future rulemaking. In the CY 2020 PFS final rule (84 FR 62797), we finalized that, in the interest of payment stability, we would continue to maintain current coding for radiation treatment services, including HCPCS G-codes with their current work RVUs and direct PE inputs, given the introduction of the RO Model, and to prevent disruption in beneficiary access to radiation treatment services. While we did not make any proposals for payment for these radiation treatment services under the PFS for CY 2023, we note that **we are reviewing our current coding and payment policies for the radiation therapy services, including whether we should adopt the revised CPT coding that was established in CY 2015 to allow for coding and payment consistency**, considering the fact that CMS finalized delaying the current start date of the ROM earlier this year. Any such changes would be addressed in future rulemaking.

See notes section for other policies included in the rule

House Bill to Prevent Physician Pay Cuts

September 13, 2022. Rep. Larry Bucshon (R-IN) and Rep. Ami Bera (D-CA) introduced the [H.R. 8800](#), the “[Supporting Medicare Providers Act of 2022](#)” which would prevent a 4.42% Medicare physician fee payment cut from taking effect on January 1, 2023.

The Supporting Medicare Providers Act of 2022

- **Would prevent a 4.42% Medicare Physician Fee Payment cut from taking effect on January 1, 2023**
- The bill is sponsored by Rep. Ami Bera (D-CA) and currently has 59 bipartisan cosponsors:
- Further actions to increase physician reimbursements are still being discussed among members
- On 9/15 a bipartisan group of eight lawmakers [asked](#) health providers, advocates, and experts to give any input on how Congress should change Medicare payments



“The AMA commends Reps. Bera and Bucshon for acknowledging the disparity between what it costs to run a physician practice and what these cuts will mean for patient care in the Medicare program. Our patients are counting on Congress to agree to a solution, and the clock is ticking,”



“The ACS strongly supports the Supporting Medicare Providers Act of 2022, which would stop the 4.42% cuts in Medicare payments that surgeons and other providers are facing on January 1st”



“The AAFP continues to advocate for payment reforms that appropriately invest in primary care and ensure physicians have the resources and flexibility they need to care for all their patients.”



OPPS and ASC Final Rule for 2023

November 2, 2022: CMS released the OPPS and ASC Final Rule ([link](#)).

340B

- For CY 2023, CMS finalized **ASP+6%** reimbursement for drugs and biologicals acquired through the 340B program
- Consistent with statutory budget neutrality requirements, to offset the increase from ASP-22.5% to ASP+6%, CMS is implementing a **-3.09% reduction in the payment rate for non-drug items and services across all hospitals**
- CMS is finalizing the proposal to continue the use of the “JG” and “TB” claims modifiers in CY 2023

Hospital Price Transparency

- In April 2022, CMS released data for the first time on hospital and skilled nursing facility mergers, acquisitions, consolidations, and changes in ownership from 2016-2022
- In the proposed rule CMS sought comment through RFI on the following:
 - If this data should be released for additional provider types
 - What other types of data should be released
 - How current data can be used to further promote transparency
- In the final rule, **CMS made no changes** but noted that they may take the comments they received into consideration in the future

Changes to the List of ASC Covered Surgical Procedures

- CMS will add 4 procedures to the ASC CPL in CY 2023
 - **Mastectomy**
 - **Lymph node biopsy or excision**
 - Removal of intravascular vena cava filter
 - Laparoscopy, gastric restrictive procedures, and removal of adjustable restrictive devices
- CMS finalized its proposal to not remove any procedures from the CPL in CY 2023

Modifier “JG”: Drug or biological acquired with 340B drug pricing program discount, reported to trigger the payment reduction.
Modifier “TB”: Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes.

See notes section for other policies included in the rule

Noridian Communication

ASP+6% returns for 2023, *and* for 2022 if providers reprocess claims

The screenshot shows the Noridian Medicare Portal website. The header includes the Noridian logo, navigation links for 'Jurisdiction F - Medicare Part B' (listing Alaska, Arizona, Idaho, Montana, North Dakota, Oregon, South Dakota, Utah, Washington, Wyoming), 'Contact Us', 'Help', 'Tools', and 'Noridian Medicare Portal (NMP) Login'. A search bar is also present. Below the header is a navigation menu with buttons for 'Browse by Topic', 'Browse by Specialty', 'Fees and News' (highlighted), 'Policies', 'Medical Review', 'Education and Outreach', 'Provider Enrollment', and 'Forms'. The main content area displays the breadcrumb 'JF Part B / Fees and News / Latest Updates / Article Detail' and a 'Share' button. On the left is a sidebar titled 'FEES AND NEWS' with links for Alerts, Bulletins, CMS MLN Connects, Email List Sign Up, Fee Schedules (highlighted), Frequently Asked Questions (FAQs), and Latest Updates. The main article title is 'Vacating Differential Payment Rate for 340B-Acquired Drugs in 2022 Outpatient Prospective Payment System Final Rule with Comment Period - Resolved 10/26/22'. The article text includes: 'Provider/Supplier Type(s) Impacted: Outpatient', 'Reason Codes: Not Applicable', 'Claim Coding Impact: Not Applicable', 'Description of Issue: CMS recently provided an update in 2022-10-13-MLNC regarding the 340B-Acquired Drugs. All Medicare Administrative Contractors (MACs) were instructed to automatically adjust claims from September 28, 2022, forward. Additional guidance is provided below under Provider/Supplier action required.', 'Noridian Action Required: Will adjust claims from September 28, 2022 forward.', 'Provider/Supplier Action Required: Although MACs shall not reprocess 2022 date of service claims paid prior to 09/28/22 as contractor-initiated adjustments, MACs shall process provider-submitted adjustments to 2022 date of service claims that were paid prior to September 28, 2022. The adjustments can be submitted using type of bill (TOB) XX7 with condition code D9 and remarks indicating "340B Adjustment".', 'Proposed Resolution/Solution: MACs will update the production alert when they have completed the adjustments from September 28, 2022 forward.', '10/26/22 - Mass adjustments have been completed.', 'Date Reported: 10/20/22', and 'Date Resolved: 10/26/22'. The footer indicates 'Last Updated Nov 03, 2022'.

Executive Order: CMMI Demo on Drugs



Oct. 14, 2022: Pres. Biden issued an Executive Order (EO) on “Lowering Prescription Drug Costs for Americans” that directs CMMI to take “additional actions to complement the IRA and further drive down prescription drug costs.”

CMMI’s mandate:

Sec. 2. HHS Actions. In furtherance of the policy set forth in section 1 of this order, the Secretary shall, consistent with the criteria set out in 42 U.S.C. 1315a(b)(2), consider whether to select for testing by the Innovation Center **new health care payment and delivery models that would lower drug costs and promote access to innovative drug therapies for beneficiaries enrolled in the Medicare and Medicaid programs, including models that may lead to lower cost-sharing for commonly used drugs and support value-based payment that promotes high-quality care.** The Secretary shall, not later than 90 days after the date of this order, submit a report to the Assistant to the President for Domestic Policy enumerating and describing any models that the Secretary has selected. The report shall also include the Secretary’s plan and timeline to test any such models. Following the submission of the report, the Secretary shall take appropriate actions to test any health care payment and delivery models discussed in the report.

Notable Timing

- The day before this EO, the Bureau of Labor Statistics announced **Sept. 2022 inflation was 8.2%**
- With midterm elections looming, this is Biden’s attempt to move the conversation away from high inflation and towards drug pricing

Next steps

- HHS will submit a **report by Jan. 14, 2023**
- Report will describe any models the Secretary has selected, including the plan and timeline to test any such models
- Following the report submission, the Secretary shall test any healthcare payment and delivery models discussed in the report

Executive Order: CMMI Demo on Drugs



What types of demos might be under consideration?



- Rumors that CMMI is focused on CAR-T specifically
- Politically, this might make sense: CAR-Ts have high prices and are unlikely to be targeted by the IRA (since primarily inpatient utilization)
- CMS attempted a CAR-T demo in Medicaid in 2017

- CMMI tried to tackle Part B drugs in 3 of the 5 drug demos thus far; they may try again

- This is the only successful drug demo to date
- CMMI’s Strategy Refresh noted the agency is considering expansion beyond insulin

- Launch prices are viewed as unfinished business from the IRA



Aug. 30, 2017:

- CMS and Novartis [announced](#) a Medicaid VBA demonstration for Kymriah focused on 30-day response. CMS viewed the VBA as an “outcome contingency” and not a “purchase contingency,” thereby dodging inclusion in Best Price and ASP calculations.

Feb. 2018:

- CMS [backed out](#) of the arrangement following scrutiny over Novartis’ alleged influence in the process.

CMMI’s Strategy Refresh (Oct. 2021)

- “CMMI will prioritize models that test ways to lower beneficiary and program spending on drugs and incentivize **biosimilar and generic** drug utilization to improve quality and beneficiary health. This could include models that test innovative payment approaches for Medicare **Part B drugs**, such as shared savings and bundled payment models for episodes of care, models that build on the **Part D Senior Savings Model** or lower **LIS cost-sharing** for biosimilar and generic drugs, or future **total cost of care** models that could include both Part B and Part D drugs.
- “While Medicaid beneficiaries’ exposure to out-of-pocket costs is more limited, they can still face co-pays and other indirect financial barriers to access care, such as lack of access to transportation, childcare, or taking time from work to attend to medical issues.”
- “Given the potential to reduce Medicare spending and beneficiary out-of-pocket costs, CMMI could consider models that include **site-neutral payments** for services offered in different settings.”

CMMI & Prescription Drugs: Recap of Past Demos

March 2016:

- [Part B Demo Proposed Rule](#)
- Mandatory participation
- Two-phase Part B drug demo:
 1. Reimburse at ASP plus 2.5% and a flat fee of \$16.80 per prescription
 2. Test the application of value-based purchasing tools, potentially including reference-based pricing, indications-based pricing, and risk-sharing agreements
- Oct. 2017: formally [withdrawn](#)

Oct. 2018

- [Part B International Pricing Index \(IPI\) ANPRM](#)
- Mandatory participation
- IPI targeted Part B drugs, would have based reimbursement on 126% of international prices and eliminated buy-and-bill, instead moving to vendor purchasing
- Proposed Rule was never released

March 2019

- [Part D Payment Modernization Model](#)
- Voluntary participation
- Part D and MAPD plans take on two-sided risk for the CMS federal reinsurance subsidy
- Jan. 2021: Trump-led CMS updated the model to eliminate the Protected Class coverage guarantee for 5 of the 6 classes (antiretrovirals would remain protected) starting 2022
- March 2021: Biden-led CMS [reversed](#) that policy change
- CMS allowed the model to expire year-end 2021

March 2020

- [Part D Senior Savings Model](#)
- Voluntary participation
- Insulin manufacturers pay increased Part D Coverage Gap discounts (70% is calculated before the application of supplemental benefits) in exchange for Part D and MAPD plans providing \$35 max copays
- Status: Ongoing

The only notable prescription drug model to be implemented

Nov. 2020

- [Part B Most Favored Nation \(MFN\) Interim Final Rule](#)
- Mandatory participation
- MFN targeted 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.
- This means that instead of ASP + 6% reimbursement, targeted drugs would have been reimbursed at an average rate of ASP – 65%
- CMS projected 19% of beneficiaries would have been forced to forgo treatment because unable to find a willing provider
- Dec. 2020: Court [blocked MFN](#) implementation for improper use of the interim final rule process

3 out of 5 past CMMI drug-related demos focused on **physician-reimbursement for Part B drugs**

State Update

Texas Election Recap

- Republicans retain their statewide offices for the 13th consecutive election cycle.
- The Legislature maintains its Republican majorities as well with expected gains through redistricting. South Texas did not flip Republican as some expected.
 - The House will have 30 new members and the Senate will have 6 new members in 2023.
 - The makeup of the House will be 86 Republicans and 64 Democrats.
 - The makeup of the Senate will be 19 Republicans and 12 Democrats.
- The expectation is that the legislative session will reflect the broad themes we have seen throughout the election cycle:
 - Securing the border – address human trafficking and drug smuggling
 - Property tax relief
 - Maintain economic growth
 - Strengthen parental rights

Upcoming Legislative Milestones

- Interim reports for House and Senate Committees will be finalized and published for public review in the next couple of months.
- November 14 – First day legislators and legislators-elect may file bills for the 88th Legislature.
- January 10 – 88th Legislature convenes at noon.
- Late January – inauguration of Governor Abbott
- Legislative committees will be named in late January/early February; the state GOP party leadership has adopted a plank that all standing committees should be chaired by Republicans.
 - The House Speaker and his lieutenants are pushing back against this, but an interesting debate on this is expected. Out of 34 standing committees last session, 11 are chaired by Democrats.
 - Currently, one Senate standing committee has a Democrat chair (Whitmire, Criminal Justice).



hello@advi.com

202.509.0760

1000 F St NW
Suite 650
Washington, DC 20004



Post Election Day, Focus Shifts to Lame Duck Session and FY2023 Government Funding

Pending results in Arizona and Nevada, 2023 Senate majority may not be known until December 6 Georgia run-off.

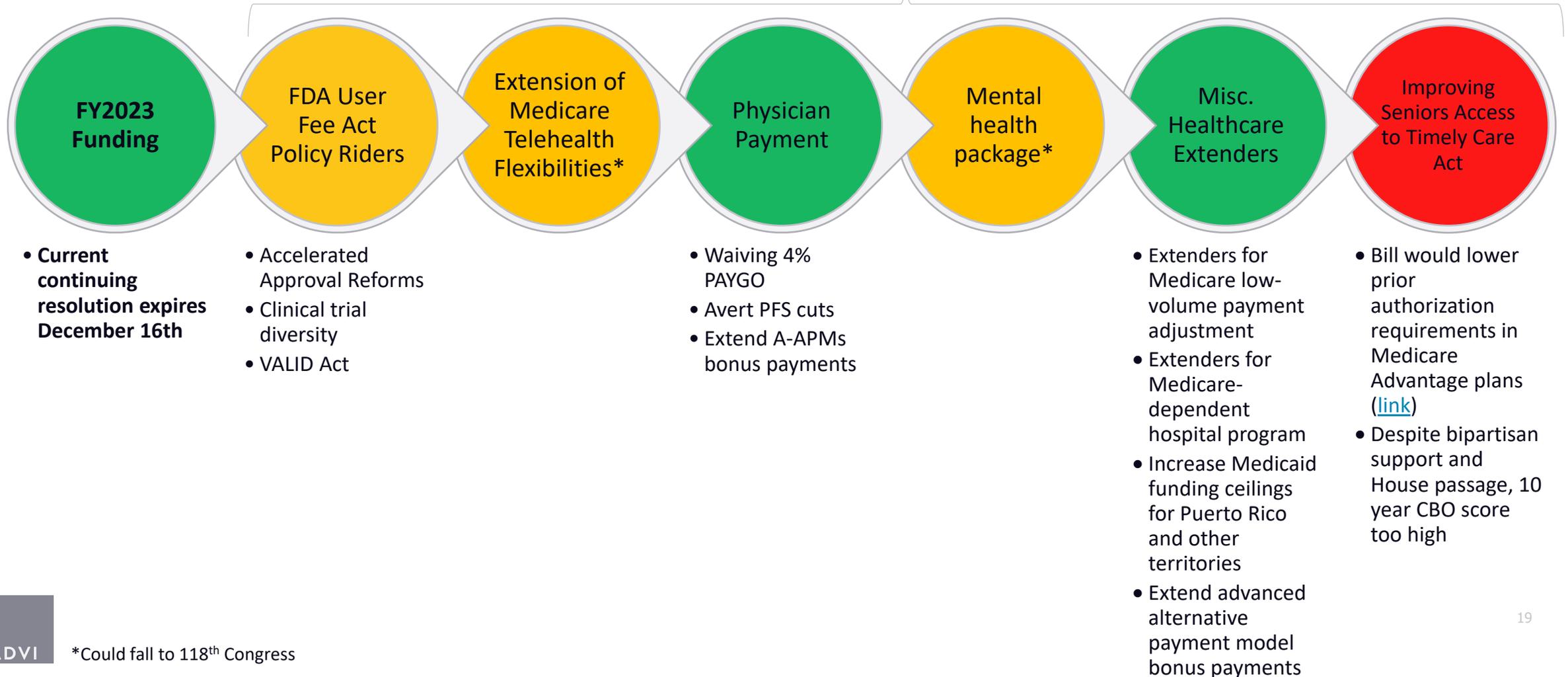
FY2023 Continuing Resolution expires December 16. Outcome of mid-terms was going to dictate composition of a year-end package (i.e., what level of bipartisanship could be expected and how many policy priorities would be included).

Final package will be a combination of expiring/must-pass elements and policy riders (analysis on next slide).

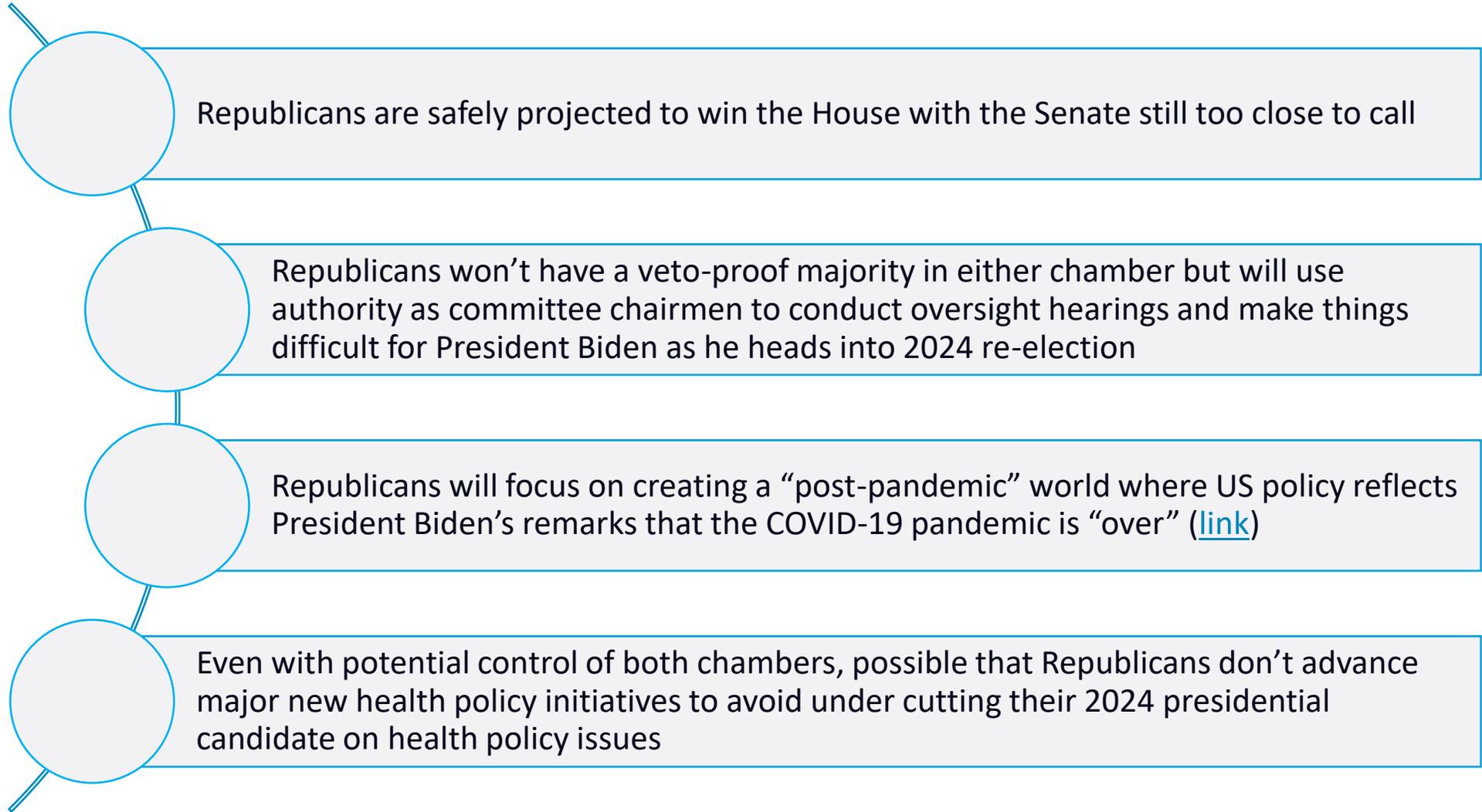
Whether the Biden Administration chooses to extend the PHE past January 11, 2023 could dictate elements of the package. Whether that extension will be granted will be known by November 12.

Post Election Day, Focus Shifts to Lame Duck Session and FY2023 Government Funding

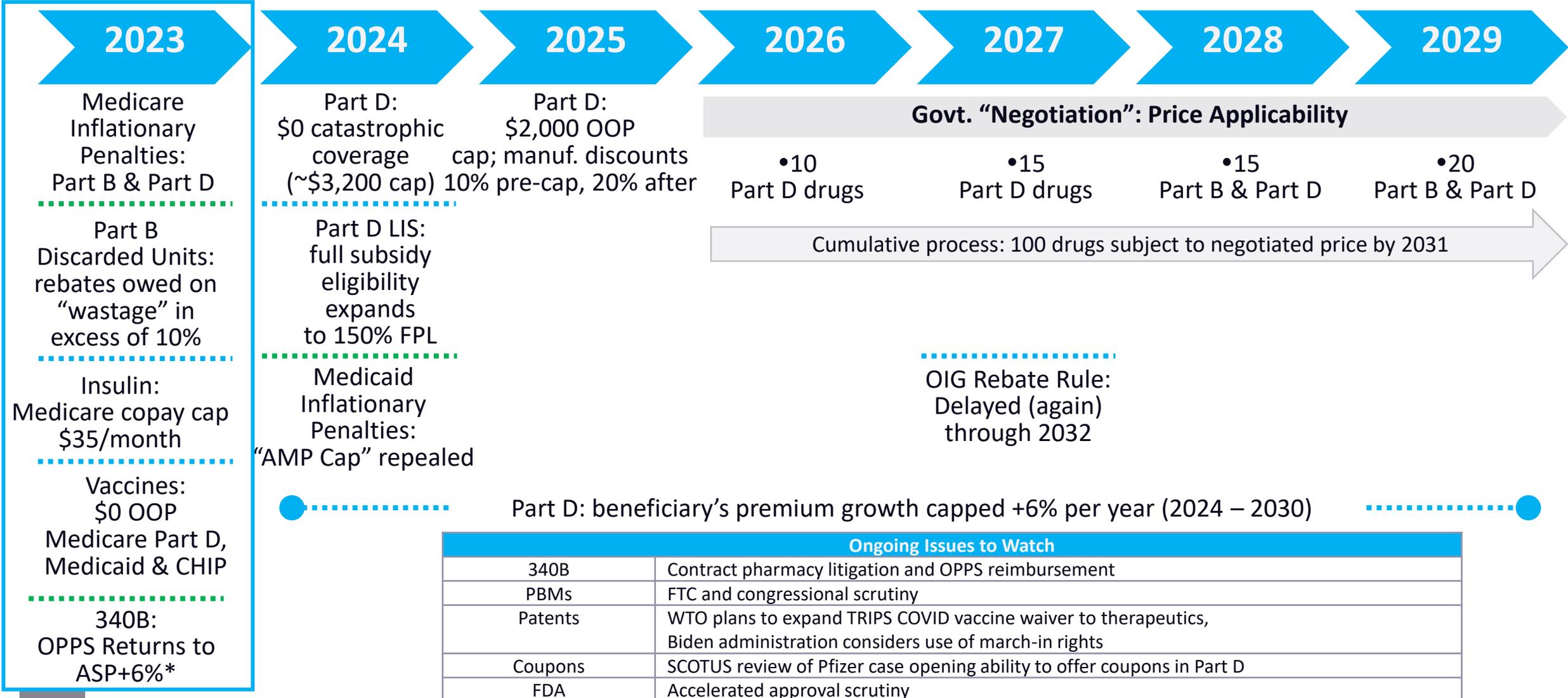
Potential Policy Riders



Dynamics at Play in Divided Government Heading into 2023



Drug Pricing Policy Horizon: Implementation Timeline



Republican Policy Priorities

House Republican's "Healthy Future Task Force" drug pricing [platform](#) outlines policy reforms the caucus plans to address should it take the majority next Congress

"Lower Drug Costs for Americans"

- Ensure patients pay the same rate for physician-administered Rx whether administered in physician office or a HOPD
- Prohibit "pay for delay" agreements
- Build on bipartisan proposals "that allow for innovations in how we pay for curative therapies"
- Point of sale rebates:
 - Offer incentives for plans to share discounts with patients directly at the pharmacy counter
- If IRA is repealed
 - Copay smoothing
 - Part D redesign/OOP cap

"Unleash New Innovative Medicines, Devices, Diagnostics for Patients"

- Broaden the FDA Accelerated Approval Program
- Speed up Medicare coverage for breakthrough drugs and devices
 - Notes the Biden administration "rejected the FDA's gold standard approval" by restricting coverage of Alzheimer's drugs
- Diagnose cancer earlier by giving seniors access to blood tests that can detect more cancers at earlier stages
- Ban the use of QALYs from all coverage and payment decisions
- Build off of COVID-19 PHE flexibilities to make clinical trials more widely available and speed up the development of new treatments and cures

"Promote American-Made Medicines"

- Incentivize domestic medal manufacturing of therapies and therapeutics
- Promote sufficient supply of testing and PPE
- "Ensure secure access to critical ingredients for medicine"

"Lower Costs and Increase Choices Through Competition"

- Pass legislation to
 - Reform the inpatient-only list
 - "End inappropriate billing practices that lead to higher costs for patients"
 - Repeal the moratorium on physician-owned hospitals
- Congressional oversight of the FTC

Republicans Eye Repeal of the IRA in 2023...

"Because those drug provisions are so dangerous, by discouraging investment in life-saving cures, I would imagine that will be a top priority for Republicans in the new session." – Rep. Kevin Brady (R-Tx)

"If the courts haven't gotten to it beforehand, yeah we've got to do our job and try to defend the Constitution." – Rep. Morgan Griffith (R-VA)

"The ongoing issues with pharmacy benefit managers, the drug pricing middlemen, were also not addressed in the Democrats' bill. We need more drug options, not less. We need more competition, not price controls. We need innovation, not stagnation." – Sen. James Lankford (R-OK)

"To prevent the IRA from wreaking havoc on American drug innovation, Congress should pass Senator Mike Lee's Protect Drug Innovation Act, which repeals these barriers to pharmaceutical competition and innovation." – Sen. Mike Lee (R-UT)

...However Political Realities Will Bring Challenges

President Biden will not sign a bill that repeals a major piece of one of his signature legislative achievements

- Unlikely that Republicans would secure margins allowing them to override a presidential veto

Repealing pieces of the Inflation Reduction Act would be expensive

- CBO scored the IRA's drug pricing policies as saving \$288B