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

Source: ABC News

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.
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.

*Georgia law requires the winning candidate to get an outright majority of the vote (>50%). Neither candidate met that threshold resulting in a run-off.
Political Timeline

Oct. 10: 8.2% inflation in Sept.

Nov. 10: Inflation data expected

Dec. 10: Inflation data expected

Oct. 14: Biden EO on Lowering Rx Costs through CMMI (link)

Nov. 8: Mid-Term Election

Nov. 12: Deadline for HHS to give notice if allowing the PHE to expire on January 11, 2023 (link)

Dec. 6: Georgia Senate Runoff

Dec. 16: Continuing Resolution Expires (link)

Jan. 1: Physician payment cuts

January 11: PHE Expires (if notice not given by 11/12) (link)

Late winter: State of the Union

Spring: Biden’s FY 2024 Budget

Jan. 1: Drug Pricing Policies Go Into Effect:
  • Part B Inflationary Rebates
  • Part B discarded units
  • $35 cap on Medicare OOP for insulin
  • $0 OOP for Part D/Medicaid vaccines
  • 340B returns to ASP+6%

Q2/Q3: Expectation that debt ceiling will be reached
### 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

### OPP

- 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

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### Radiation therapy services mentioned:

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.”

Sources: Rep. Bera (link), POLITICO (link)
OPPS and ASC Final Rule for 2023

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

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<tr>
<th>340B</th>
<th>Hospital Price Transparency</th>
<th>Changes to the List of ASC Covered Surgical Procedures</th>
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<tr>
<td>• For CY 2023, CMS finalized ASP+6% reimbursement for drugs and biologicals acquired through the 340B program</td>
<td>• 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</td>
<td>• CMS will add 4 procedures to the ASC CPL in CY 2023</td>
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<td>• 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</td>
<td>• In the proposed rule CMS sought comment through RFI on the following:</td>
<td>• Mastectomy</td>
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<td>• CMS is finalizing the proposal to continue the use of the “JG” and “TB” claims modifiers in CY 2023</td>
<td>• If this data should be released for additional provider types</td>
<td>• Lymph node biopsy or excision</td>
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<td>• What other types of data should be released</td>
<td>• Removal of intravascular vena cava filter</td>
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<td>• How current data can be used to further promote transparency</td>
<td>• Laparoscopy, gastric restrictive procedures, and removal of adjustable restrictive devices</td>
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<td>• In the final rule, CMS made no changes but noted that they may take the comments the received into consideration in the future</td>
<td>• CMS finalized its proposal to not remove any procedures from the CPL in CY 2023</td>
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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
ASP+6% returns for 2023, and for 2022 if providers reprocess claims
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
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.

Aug. 30, 2017:

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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

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<tr>
<td><strong>Part B Demo Proposed Rule</strong></td>
<td><strong>Part B International Pricing Index (IPI) ANPRM</strong></td>
<td><strong>Part D Payment Modernization Model</strong></td>
<td><strong>Part D Senior Savings Model</strong></td>
<td><strong>Part B Most Favored Nation (MFN) Interim Final Rule</strong></td>
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<tr>
<td>Mandatory participation</td>
<td>Mandatory participation</td>
<td>Voluntary participation</td>
<td>Voluntary participation</td>
<td>Mandatory participation</td>
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<tr>
<td>Two-phase Part B drug demo:</td>
<td>IPI targeted Part B drugs, would have based reimbursement on 126% of international prices and eliminated buy-and-bill, instead moving to vendor purchasing</td>
<td>Part D and MAPD plans take on two-sided risk for the CMS federal reinsurance subsidy</td>
<td>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</td>
<td>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.</td>
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<td>Oct. 2017: formally withdrawn</td>
<td>Proposed Rule was never released</td>
<td>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</td>
<td>March 2021: Biden-led CMS reversed that policy change</td>
<td>This means that instead of ASP + 6% reimbursement, targeted drugs would have been reimbursed at an average rate of ASP – 65%</td>
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| 3 out of 5 past CMMI drug-related demos focused on physician-reimbursement for Part B drugs | | March 2021: Biden-led CMS | March 2021: Biden-led CMS reversed that policy change | | | CMS allowed the model to expire year-end 2021 | | | Status: Ongoing |}

The only notable prescription drug model to be implemented

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The only notable prescription drug model to be implemented.
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).
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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.
Improving Seniors Access to Timely Care

• Bill would lower prior authorization requirements in Medicare Advantage plans (link)
• Despite bipartisan support and House passage, 10 year CBO score too high

Mental health package*

• Extenders for Medicare low-volume payment adjustment
• Extenders for Medicare-dependent hospital program
• Increase Medicaid funding ceilings for Puerto Rico and other territories
• Extend advanced alternative payment model bonus payments

Misc. Healthcare Extenders

• Increase Medicaid funding ceilings for Puerto Rico and other territories

Physician Payment

• Waiving 4% PAYGO
• Avert PFS cuts
• Extend A-APMs bonus payments

Extension of Medicare Telehealth Flexibilities*

• Accelerated Approval Reforms
• Clinical trial diversity
• VALID Act

FDA User Fee Act Policy Riders

• Current continuing resolution expires December 16th

Potential Policy Riders

FY2023 Funding

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

*Could fall to 118th Congress
Republicans are safely projected to win the House with the Senate still too close to call.

Republicans won’t have a veto-proof majority in either chamber but will use authority as committee chairmen to conduct oversight hearings and make things difficult for President Biden as he heads into 2024 re-election.

Republicans will focus on creating a “post-pandemic” world where US policy reflects President Biden’s remarks that the COVID-19 pandemic is “over” (link).

Even with potential control of both chambers, possible that Republicans don’t advance major new health policy initiatives to avoid under cutting their 2024 presidential candidate on health policy issues.
Drug Pricing Policy Horizon: Implementation Timeline

2023
- Medicare Inflationary Penalties: Part B & Part D
- Part B Discarded Units: rebates owed on “wastage” in excess of 10%
  - Insulin: Medicare copay cap $35/month
  - Vaccines: $0 OOP Medicare Part D, Medicaid & CHIP
- 340B: OPPS Returns to ASP+6%*

2024
- Part D: $0 catastrophic coverage (~$3,200 cap)
- Part D: $2,000 OOP cap; manuf. discounts 10% pre-cap, 20% after
- Part D LIS: full subsidy eligibility expands to 150% FPL
- Medicaid Inflationary Penalties: “AMP Cap” repealed

2025
- Part D: beneficiary’s premium growth capped +6% per year (2024 – 2030)

2026
- Govt. “Negotiation”: Price Applicability
  - Part D: first 10 drugs
  - Part D: next 15 drugs

2027
- Part B & Part D: first 15 drugs
- Part D: next 20 drugs

2028

2029

Ongoing Issues to Watch

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<tr>
<th>Issue</th>
<th>Description</th>
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<tr>
<td>340B</td>
<td>Contract pharmacy litigation and OPPS reimbursement</td>
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<td>PBMs</td>
<td>FTC and congressional scrutiny</td>
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<td>Patents</td>
<td>WTO plans to expand TRIPS COVID vaccine waiver to therapeutics, Biden administration considers use of march-in rights</td>
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<td>Coupons</td>
<td>SCOTUS review of Pfizer case opening ability to offer coupons in Part D</td>
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<td>FDA</td>
<td>Accelerated approval scrutiny</td>
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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

<table>
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<th>Republican Policy Priorities</th>
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<td><strong>“Lower Drug Costs for Americans”</strong></td>
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<td>• Ensure patients pay the same rate for physician-administered Rx whether administered in physician office or a HOPD</td>
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<td>• Prohibit “pay for delay” agreements</td>
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<td>• Build on bipartisan proposals “that allow for innovations in how we pay for curative therapies”</td>
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<td>• Point of sale rebates:</td>
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<td>• Offer incentives for plans to share discounts with patients directly at the pharmacy counter</td>
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<td>• If IRA is repealed</td>
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<td>• Copay smoothing</td>
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<td>• Part D redesign/OOP cap</td>
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<td><strong>“Unleash New Innovative Medicines, Devices, Diagnostics for Patients”</strong></td>
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<td>• Broaden the FDA Accelerated Approval Program</td>
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<td>• Speed up Medicare coverage for breakthrough drugs and devices</td>
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<td>• Notes the Biden administration “rejected the FDA’s gold standard approval” by restricting coverage of Alzheimer’s drugs</td>
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<td>• Diagnose cancer earlier by giving seniors access to blood tests that can detect more cancers at earlier stages</td>
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<td>• Ban the use of QALYs from all coverage and payment decisions</td>
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<td>• Build off of COVID-19 PHE flexibilities to make clinical trials more widely available and speed up the development of new treatments and cures</td>
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<td><strong>“Promote American-Made Medicines”</strong></td>
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<td>• Incentivize domestic medal manufacturing of therapies and therapeutics</td>
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<td>• Promote sufficient supply of testing and PPE</td>
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<td>• “Ensure secure access to critical ingredients for medicine”</td>
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<td><strong>“Lower Costs and Increase Choices Through Competition”</strong></td>
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<td>• Pass legislation to</td>
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<td>• Reform the inpatient-only list</td>
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<td>• “End inappropriate billing practices that lead to higher costs for patients”</td>
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<td>• Repeal the moratorium on physician-owned hospitals</td>
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<td>• Congressional oversight of the FTC</td>
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Source: Republican Healthy Future Task Force Affordability Subcommittee One pager (link)
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)
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