

# TxSCO Update

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July 11, 2024  
ADVI & HillCo



## Federal

- 2024 Election
- New Medicare Part B Drug Reimbursement Proposal
- AMA Supports Legislation to Replace MIPS with DPPS
- Supreme Court Rulings: Healthcare Implications
- Energy and Commerce Advances Stark Law Reform
- CBO 340B Spending Data for 2010-2021
- NIH Announces New AI Immunotherapy Tool for Cancer Treatment

## State

- TMB Final Rules related to abortion exemptions
- Speaker politics

# 2024 Election: Debate Fallout



# New Medicare Part B Drug Reimbursement Proposal from Former Trump Advisor

June 18, 2024: Theo Merkel (former Trump National Economic Council) released a proposal that would tie coverage and reimbursement of new Part B drugs to manufacturers contracting with a threshold of Medicare Advantage (MA) plans.

## Coverage

MA plans would not initially be required to cover “novel” therapies under Part B



Instead, each year, MA plans would have the opportunity to negotiate a contract with the manufacturer to cover a given drug at a mutually agreed-upon price



If a threshold of plans (e.g., 50% by enrollment) achieve such a contract, the drug would be required to be covered by Medicare (MA and fee-for-service (FFS))\*



If the coverage threshold is not met, the drug would not be covered by Medicare for the next year and the process would repeat for the next plan year

## Provider Reimbursement

### Buy-and-bill remains intact

- This proposal keeps buy-and-bill intact, as opposed to the IPI\*\* which would have established a “CAP 2.0” vendor model

### Medicare Advantage

- The highest-priced contract above the “volume threshold” would determine the “clearing price” for the drug, which would be used to set the price of the drug as well as reimbursements to MA plans
- **Manufacturers would be required to sell the drug for, at most, the clearing price minus 1%**
- MA plans that reached a contract would receive reimbursement equal to the clearing price minus 1%
- MA plans that did not reach a contract would receive reimbursement equal to the clearing price

### Fee-For-Service

- The clearing price would be used to set the reimbursement rates paid to providers who see traditional FFS Medicare beneficiaries
- **Instead of being reimbursed at ASP + 6%, providers would be reimbursed at the clearing price plus “an add-on payment”**



While former President Trump remains focused on international reference pricing (IRP), Merkel argued IRP is not appropriate for *new* Part B drugs, as these therapies are often not available ex-US until one or more years following the US launch.

Merkel also noted the IRA’s price controls do not address *new* Part B drugs, as biologics are ineligible for price controls for 13 years post launch, and small-molecule drugs are ineligible for 9 years.

Under a Trump 2.0 administration, CMMI could pursue an IRP approach for *older* Part B drugs and this proposal for *new* Part B drugs.

\*All MA plans would be required to cover the drug, but they would also be reimbursed separately, outside the capitated payment for this subset of drugs

\*\*IPI: International Pricing Index Model ([link](#)); MFN: Most Favored Nation Model ([link](#))

Source: Manhattan Institute, “How to Deliver Lower Prices for Seniors A Market-Based Reform for Expensive Drugs with Limited Competition” (6/18/24, [link](#))



# New Medicare Part B Drug Reimbursement Proposal from Former Trump Advisor

Under both examples listed below, the contract threshold for guaranteed coverage is 50% of plans (by enrollment)

## Figure 1

Two examples of how the process might play out.

### Example 1:

Insurer 1 \$1,000 28% of enrollment	Insurer 2 \$2,000 18% of enrollment	Insurer 3 \$3,000 12% of enrollment	Insurer 4 \$4,000 6% of enrollment	Insurer 5 No contract 5% of enrollment
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**Outcome:** The drug must be covered and the manufacturer must sell at clearing price of \$2,970. Reimbursement to Medicare Advantage plans 1 through 4 set at \$2,970. Reimbursement for plan 5 set at \$3,000. Fee-for-service reimbursement set at \$3,000 plus an administration fee.

### Example 2:

Insurer 1 \$45,000 18% of enrollment	Insurer 2 \$50,000 5% of enrollment	Insurer 3 \$80,000 12% of enrollment	Insurer 4 No contract 28% of enrollment	Insurer 5 No contract 6% of enrollment
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**Outcome:** Medicare Advantage plans with only 35% of enrollment reached a deal to cover this drug. Therefore, the drug would not be covered by Medicare and the contracting process would start again the next year.

## ADVI Advisor Insights

- Negative impact on innovation given the non-guarantee of Medicare coverage
- Expect higher Part B drug launch prices to account for the model
- MA plan incentives: The proposal claims that “MA plan sponsors want to cover as many drugs as possible in order to make the plan attractive to potential enrollees,” but our advisors disagree because MA enrollees do not typically choose plans with Part B drug coverage in mind (e.g., an enrollee is not expecting to be diagnosed with cancer next year, therefore they will not pick a plan based on its coverage of the newest cancer drugs)

## Lingering Questions

- ASP implications: if Part B sales at the mandated price are included in the ASP calculation, the model could result in lower provider reimbursement with commercial and Medicaid patients (i.e., the “ASP spiral” concern with Part B drugs subject to a negotiated price under the IRA)
- Negotiation timeline and mid-year launch implications: an advisor noted negotiation might align with the Part D formulary calendar, meaning it may be a full year from time of approval until clear Medicare coverage
- Role of compendia in coverage decisions
- Treatment of combination therapies

# New Medicare Part B Drug Reimbursement Proposal from Former Trump Advisor

Under the proposal, provider reimbursement for Part B drugs will be based on the clearing price. Examples below outline provider reimbursement for Figure 1, Example 1 on the previous slide.

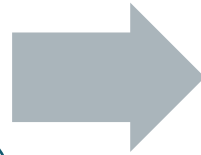
Current Policy		Proposed Policy	
<b>ASP</b>	\$4,000	<b>Clearing Price</b>	\$3,000
<b>Purchase Price (assumes no discounts)</b>	\$4,000	<b>Purchase Price (Clearing Price – 1%)</b>	\$2,970
<b>Reimbursement (ASP + 6%)</b>	\$4,240	<b>Reimbursement (Clearing Price + “add-on payment”)</b>	\$3,000 + “add-on payment”
<b>Provider Earnings</b>	<b>\$240</b>	<b>Provider Earnings</b>	<b>\$30 + add-on payment</b>

# AMA Supports Legislation to Replace MIPS with DPPS

The American Medical Association (AMA) supports draft legislation to **replace the Merit-Based Incentive Payment System (MIPS) with the proposed Data-Driven Performance Payment System (DPPS)** with the goal of reducing administrative burden and improving patient outcomes and quality of care.

## Current System: Merit-Based Incentive Payment System (MIPS)

- Penalizes doctors who score below the performance threshold and rewards those who score above with bonuses
- AMA criticisms:
  - Substantial **administrative burden**
  - Fails to improve patient outcomes or quality of care
  - **Does not provide timely feedback** for physicians to improve their practices



## Alternative System: Data-Driven Performance Payment System (DPPS)

- Per AMA:
  - Aligns yearly payment updates with physician performance
  - **Exempt doctors from penalties** if CMS fails to provide a quarterly feedback report
  - Automatically gives physicians credit for measures that achieve many MIPS goals
- AMA beliefs:
  - **Alleviate administrative burden** by simplifying reporting requirements
  - Ensure timely and accountable data sharing from CMS



**James Madara**  
CEO and Executive VP  
American Medical Association

“By replacing the current tournament model of payment adjustments with a more sustainable approach tied to annual payment updates, incentivizing CMS to share data with physicians, and improving the underlying measures, **DPPS would transform MIPS into the workable program Congress originally envisioned** aimed at improving patient care and reducing avoidable costs.”

The AMA recommends a **three-year hold on the performance threshold** under the newly proposed DPPS model. The AMA supports lowering the performance threshold to 60 points starting in 2025 from the set 75 points in 2024 to support adaptation to DPPS.

Note: Draft text has not yet been released as of June 25, 2024. Above content is based on press and AMA comments.

Source: IHP (6/24/24, [link](#)); AMA (6/7/24, [link](#); 6/12/24, [link](#))

# Supreme Court Rulings: Healthcare Implications

On June 28, the Supreme Court ruled to overturn the principle of Chevron deference in *Relentless, Inc. v. Dep't of Commerce* (decided 6-3) and *Loper Bright Enterprises v. Sec. of Commerce* (decided 6-2). On June 27, the Supreme Court ruled in *SEC v. Jarkesy* (decided 6-3) that when the SEC seeks civil monetary penalties (CMPs) against a defendant, that defendant is entitled to a jury trial.

## Overturn of *Chevron* Impact

- The Court's decision to overturn Chevron deference will **require Congress to draft less ambiguous legislation** to provide the framework for agencies
  - Policy counsel and trade associations could play an increasingly key role in drafting legislation due to subject matter expertise
- Impact on 340B Contract Pharmacies
  - HRSA has issued guidance on requiring 340B prices to be offered to covered entities' contract pharmacies – not regulation
    - Chevron deference applies to rulemaking/regulation, not sub-regulatory guidance
  - HRSA may be less likely to formalize this policy in regulation; if they choose to do so, they will likely face lawsuits alleging the agency is exceeding statutory authority

## *SEC v. Jarkesy* Impact

- The Supreme Court ruled that the 7<sup>th</sup> amendment's right to a jury trial applies to "suits at common law," including statutory claims that are "legal in nature," like CMPs
  - The Court applied this to the SEC's issuance of CMPs, ruling that a trial by jury is necessary
- While the case applies only to the SEC, **other agencies may face increased scrutiny on their use of CMPs**
  - CMS can impose CMPs in response to information blocking and in the IRA's Drug Negotiation Program
  - HHS OIG can impose CMPs for HIPAA violations
  - FDA can assess CMPs against numerous companies for failure to comply with certain requirements



# Energy and Commerce Advances Stark Law Reform

June 12, 2024: House Energy and Commerce Committee unanimously advanced 13 health related bills, including the Seniors' Access to Critical Medications Act.

Bill	Summary	Revisions Made in Markup	Vote
Seniors' Access to Critical Medications Act (H.R.5526)	Clarifies that delivering medicines by mail, courier, or other methods and allowing a family member or caregiver to pick up medicines on behalf of a patient would not violate the Stark Law.	<ul style="list-style-type: none"><li>• Flexibilities would last until December 31, 2029, before needing to be reauthorized</li><li>• Requires doctor and patient to meet physician in-person at least once annually</li><li>• Requires CMS to conduct a study on the impact of the flexibilities on utilization and costs</li><li>• Additional inclusion criteria for Medicare coverage of external infusion pumps and non-self-administrable drugs</li></ul>	41-0



Rep. Pallone (D-NJ-6) supported the amendments to the Seniors' Access to Critical Medications Act, saying the exception would help patients while “protecting Medicare beneficiaries by ensuring provider decisions are made on basis of clinical criteria.”

# CBO 340B Spending Data for 2010-2021

On June 17, 2024, CBO released data on the growth of the 340B program from 2010 to 2021 by drug class, facility type, and contract pharmacy status.

## Overview

- CBO found that from 2010-2021:
  - **340B spending grew 19% annually**, to \$44 billion
  - 73% of spending growth was attributable to cancer drugs, anti-infectives, and immunosuppressants

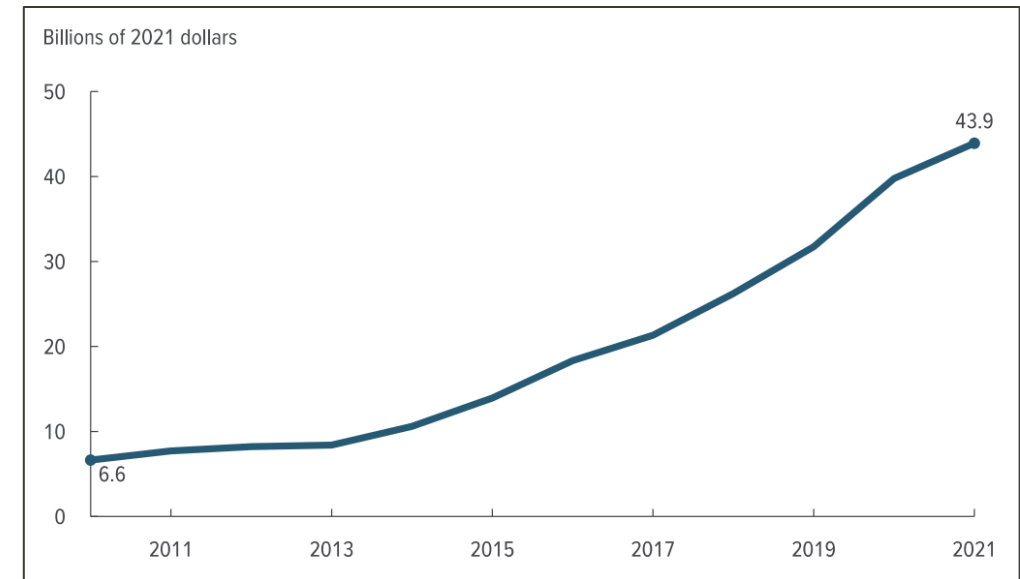
## Key findings

- CBO concluded that **only a portion of the growth in 340B spending could be explained by market trends or disproportionate spending growth for certain drug classes**
- CBO calculated that **88% of the growth in 340B spending from 2010 to 2021 can be attributed to spending on drugs prescribed by hospitals and their affiliated off-site clinics**
  - CBO further attributed 20% of the growth in 340B spending to drugs dispensed at contract pharmacies
- 47% of 340B spending at hospital-based facilities in 2021 was on cancer treatments
  - In contrast, 77% of 340B spending by federal grantees was on anti-infective agents

## Other factors which likely contributed to 340B spending growth

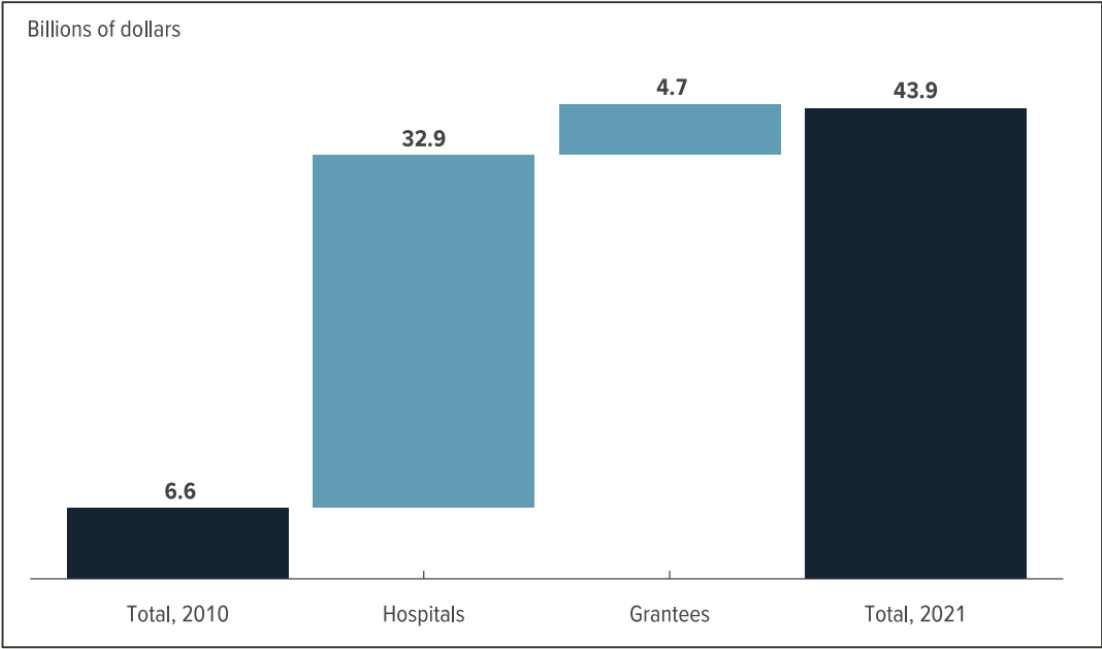
- Integration of hospitals and clinics
- Expanded facility participation under the Affordable Care Act
- Expanded use of contract pharmacies.

Spending in the 340B Program, 2010 to 2021

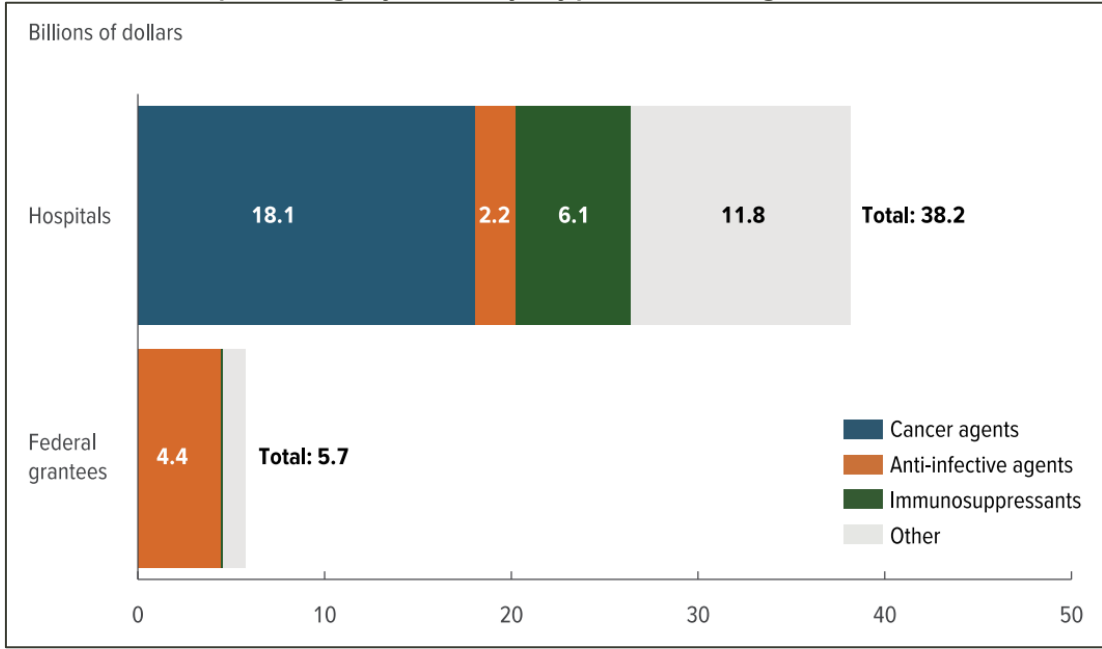


# CBO 340B Spending Data for 2010-2021

### Growth in 340B Spending by Facility Type, 2010 to 2021



### 340B Spending by Facility Type and Drug Class in 2021



Source: CBO Spending in the 340B Drug Pricing Program, 2010 to 2021 (6/17/24; [link](#))

# NIH Announces New AI Immunotherapy Tool for Cancer Treatment

On June 3, 2024, the NIH unveiled the Logistic Regression-Based Immunotherapy Response Score (LORIS) tool, which assesses the likelihood of response to immune checkpoint blockade therapy.

## LORIS

- Uses AI and machine learning to determine the potential impact of immune checkpoint inhibitors (tumor mutational burden and PD-L1) on cancer patients
- Uses six criteria to assess whether a patient's cancer will respond to immune checkpoint inhibitors
  - Age
  - Cancer type
  - History of systemic therapy
  - Blood albumin level
  - Blood neutrophil-to-lymphocyte ratio
  - Tumor mutational burden

## Accuracy

- Researchers from NCI and Memorial Sloan Kettering found that the model accurately predicted:
  - A patient's likelihood of responding to an immune checkpoint inhibitor
  - Patient lifespan; specifically, higher LORIS scores predicted better overall survival response for all except one individual cancer type (pancreatic)
  - Patients with low tumor mutational burden who could be effectively treated with immunotherapy
- **Researchers also noted that larger studies are needed to further evaluate the model in clinical settings**

Researchers compiled a dataset of 2,881 participants with 18 solid tumor types, including data from Memorial Sloan Kettering



To assess patient outcomes, researchers measured objective response, progression-free survival, and overall survival response



**Your Information**

Patient age (years): 65

Cancer type: Small cell lung cancer

Previous systemic therapy: no

Blood albumin (g/dL): 3.5

Blood neutrophil-to-lymphocyte ratio: 8

Tumor mutational burden (mut/Mb): 56

**Your result**

The likelihood of response to immune checkpoint blockade therapy (95% confidence interval)

**72%**

(60 - 83%)

This result predicts how likely you are to respond to immune checkpoint blockade therapy. The likelihood means that out of 100 patients with similar characteristics, approximately 72 may benefit from this therapy. More specifically, we're 95% confident that 60 - 83 out of 100 patients may benefit from this therapy, based on our training data. However, it's important to recognize that this is just a rough ballpark estimate. Individual patient outcomes can vary significantly, and a healthcare provider can provide a more precise assessment, taking into account a broader range of factors and personal medical history.

**Disclaimer:** This tool is provided for informational purposes only and should **NOT** be considered as medical advice or a



# State Updates



# Texas Medical Board Final Rule

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- On June 21, 2024, the Texas Medical Board adopted [final rules](#) regarding exceptions to the ban on abortions.
- The board issued these final rules after receiving feedback from private citizens, physicians, and associations.
- The adopted version of the rules specifically addresses concerns that references to ectopic pregnancy better track with existing statutory references on the matter.
- The rules stresses that the lack of imminent risk of death or substantial impairment to a patient should not preclude a physician from doing what is medically necessary.
- The rules also reaffirm that documentation in the medical records of a physician's actions and reasoning should be done in a manner that helps explain actions taken, but not slow down or preempt what may need to be done quickly to save the life of a woman.



# Speaker Politics

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- The race for House Speaker continues to dominate discussions regarding next session.
- For the time being, it seems Speaker Phelan has the necessary support to maintain his position, however, opposing factions continue to attempt to draw his supporters away and erode his credibility.
- Regardless of who becomes Speaker, the next session will present challenges between the House and the Senate.



# APPENDIX



# Fifth Circuit Court of Appeals Partially Reverses *Braidwood v. Becerra* Ruling

On June 21, 2024, the Fifth Circuit Court of Appeals reversed a District Court ruling that previously blocked the enforcement of the ACA's requirement for employer plans to cover preventive care. However, the court also said that the plaintiffs could not be forced to provide its workers with insurance that covers the services.

## Previous Activity

**-Sept. 7, 2022:** In the U.S. District Court for the Northern District of Texas, Judge Reed O'Connor ruled the ACA's delegation to USPSTF violates the Appointments Clause because the HHS Secretary cannot direct USPSTF to give a specific preventive service an "A" or "B" Rating

-HHS Secretary does not have any authority to direct which services are covered under §300gg-13(a)(1) and concludes that USPSTF members are officers of the United States and that their selection does not comply with the Appointments Clause procedures.

-The Court also found that the ACA's delegation to ACIP and HRSA are not in violation of the Appointments Clause since the HHS Secretary effectively has the authority to ratify or not the ACIP and HRSA recommendations.

**-March 30, 2023:** Judge O'Connor issued a ruling to block HHS from enforcing the ACA's requirement that private health insurers cover without cost sharing all services rated "A" or "B" by the USPSTF

-This ruling applies the decision nationally

-The ruling also eliminates the PrEP-specific coverage requirement on grounds that it violates the Religious Freedom Restoration Act (RFRA)

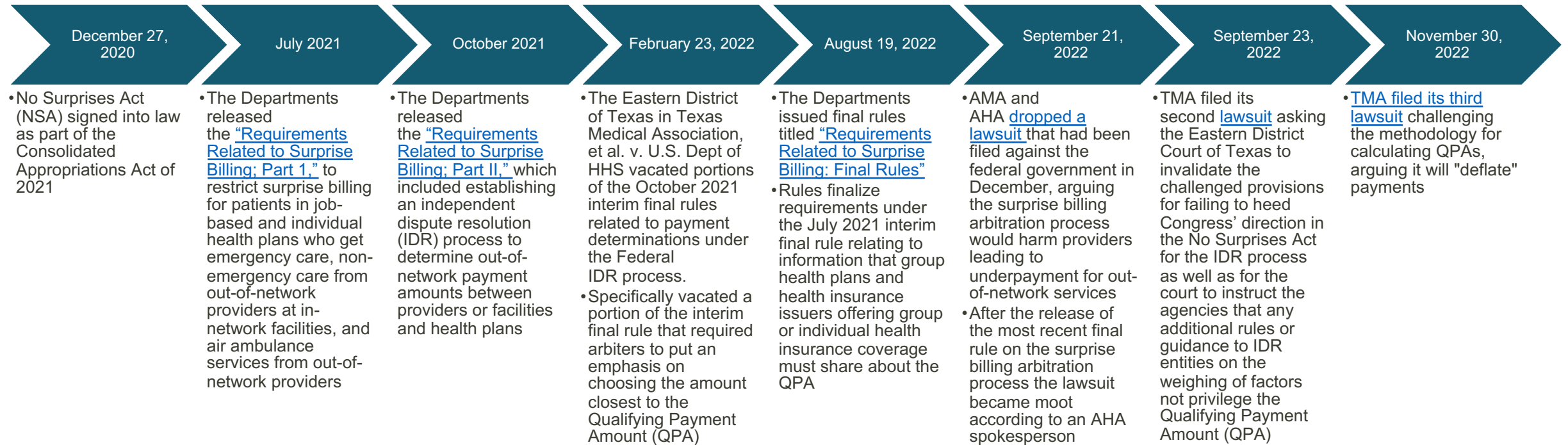
### Next Steps:

- The case will return to the Texas District Court which will hear arguments on whether the USPTF has the proper authority to decide what services insurers must cover
- The plaintiffs can appeal the Fifth Circuit Court decision to the Supreme Court before the District Court issues a decision

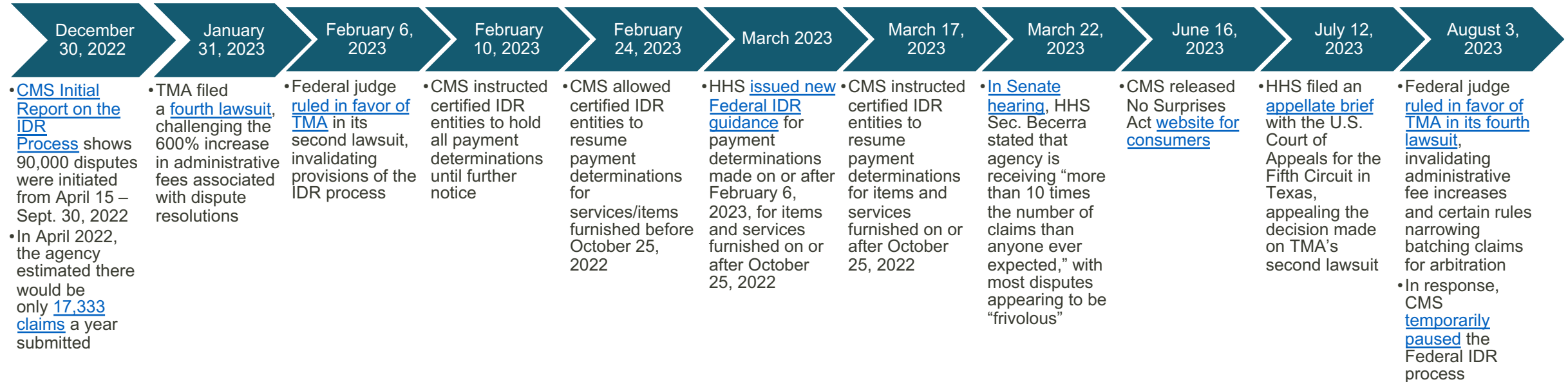
**The Fifth Circuit Court agreed with the plaintiffs that the USPTF members were not "validly appointed," but countered that the district court's decision to "universally enjoin" its ruling nationally was "an error."**

Overall, stakeholders from both sides have expressed mixed reactions to the decision. Advocates of the preventive service coverage requirements are "thankful" that coverage has been preserved but are concerned about the long-term potential USPSTF-related requirements to be weakened. Experts have suggested that the decision opens the possibility of other employers using the ruling to evade providing insurance that would cover these services. **While it is not certain whether the case will be taken up by the Supreme Court, an appeal could be filed this summer and heard by the high court as early as next term.**

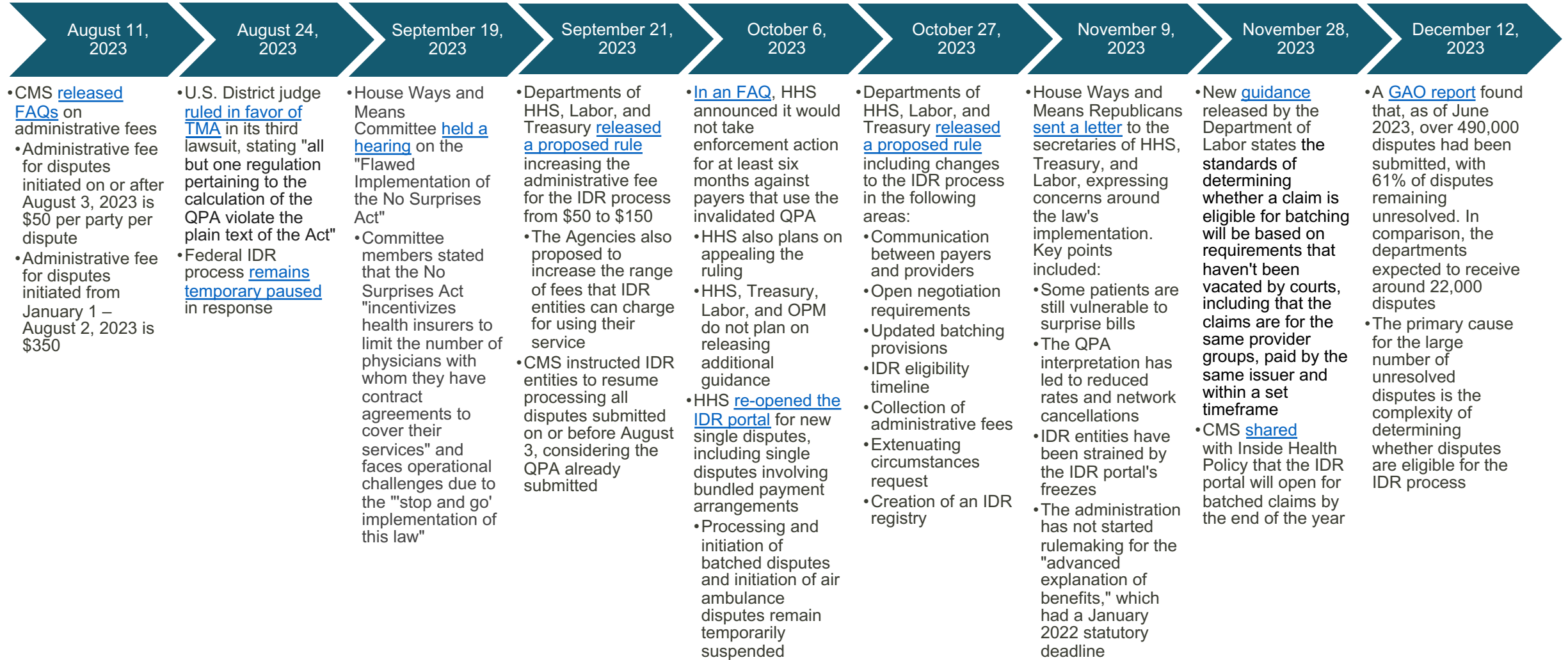
# No Surprises Act: Timeline



# No Surprises Act: Timeline

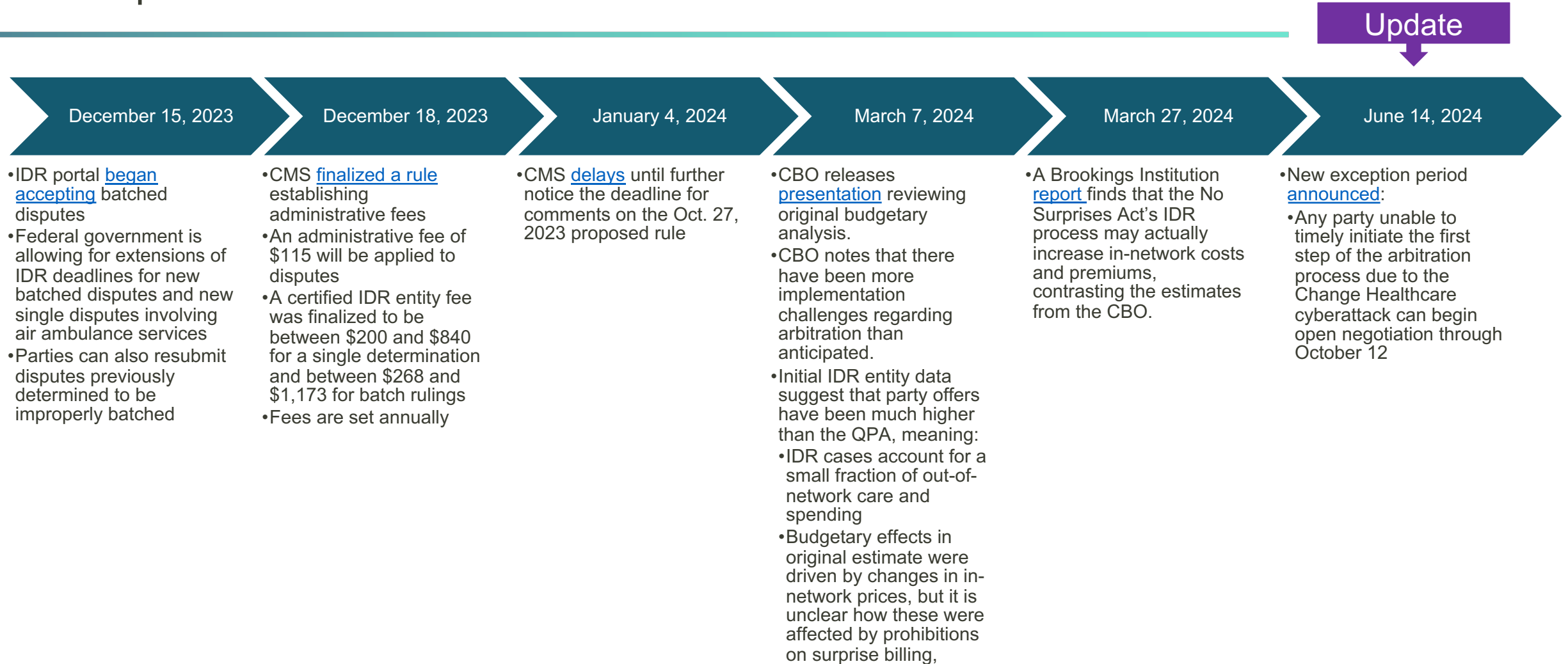


# No Surprises Act: Timeline





# No Surprises Act: Timeline



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*Thank  
You*

