



ADVI

# Federal & State Policy Updates

TxSCO

Sept. 23, 2023



# Federal Updates

# Key Federal Policy Issues

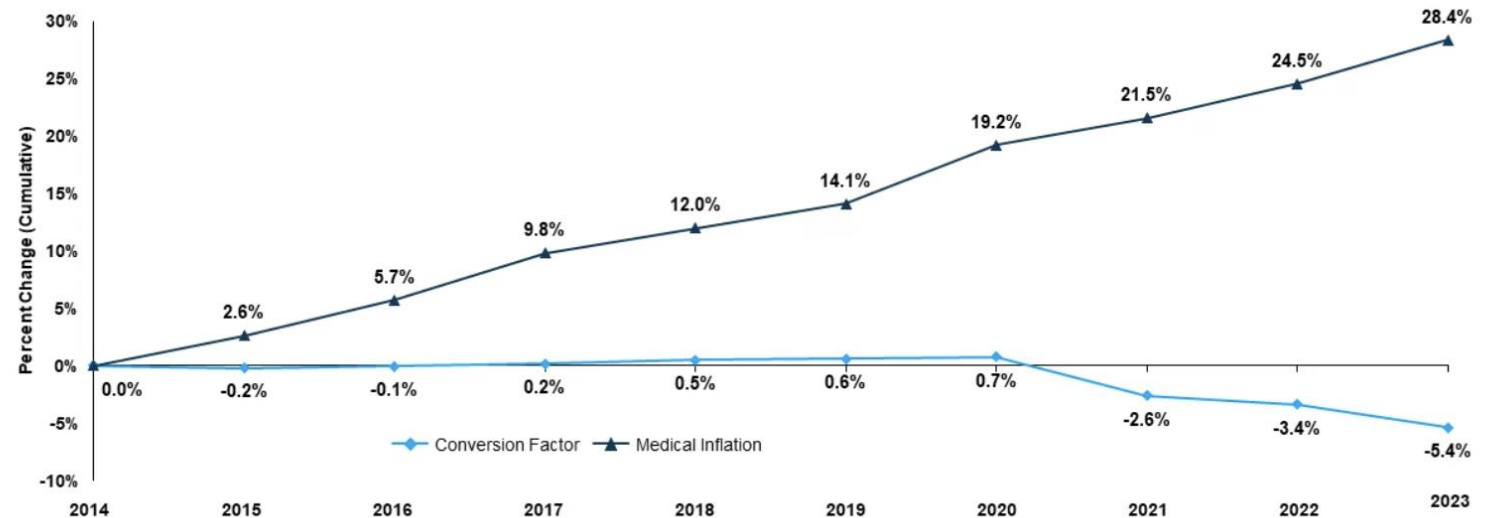
- Medicare PFS Reimbursement Cuts
- EOM Underway
- Medicaid Enrollment Shifts
- Stark Law & In-Office Dispensing: Mail-Order Prescriptions
- No Surprises Act
- Prescription Drug Pricing: “Government Negotiation” Underway

# PFS Proposed Rule 2024: More Conversion Factor Cuts

## PFS Proposed Rule for 2024: Conversion Factor

- Proposed conversion factor for CY 2024 is \$32.75, a 3.3% decrease from \$33.89 in CY 2023
- Table 104 includes a breakdown by specialty of estimated payment changes based on the proposed rule
- Notable estimates include
  - Endocrinology: +3%
  - Family Practice: +3%
  - Hematology/Oncology: +2%
  - 7 other Specialties: +2%
  - Interventional Radiology: -4%
  - Nuclear Medicine: -3%
  - Radiology: -3%
  - Vascular Surgery: -3%
  - Radiation Oncology & Radiation Therapy Centers: -2%
  - 13 other Specialties: -2%

CPI-U Medical v. Conversion Factor



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From COA/Avalere

# Enhancing Oncology Model (EOM)

Oct. 2022

- Non-binding applications due (non-binding)

May 19, 2023

- Practices received data
- “Data is out, but not what was expected to make decisions.”

June 27, 2023

- CMMI announced 67 practices will participate
- Multiple reports of CMMI inaccuracy

July 12, 2023

- CMMI revised participants: 44 practices and 3 payers

April 12, 2023

- Providers received agreements
- Raises new questions, as practices expected to use the data from CMMI to inform their decision
- Clarification sought on penalties
- Provider Insight: “There is some confusion over how this works; we’ve reached out to CMMI for clarity”

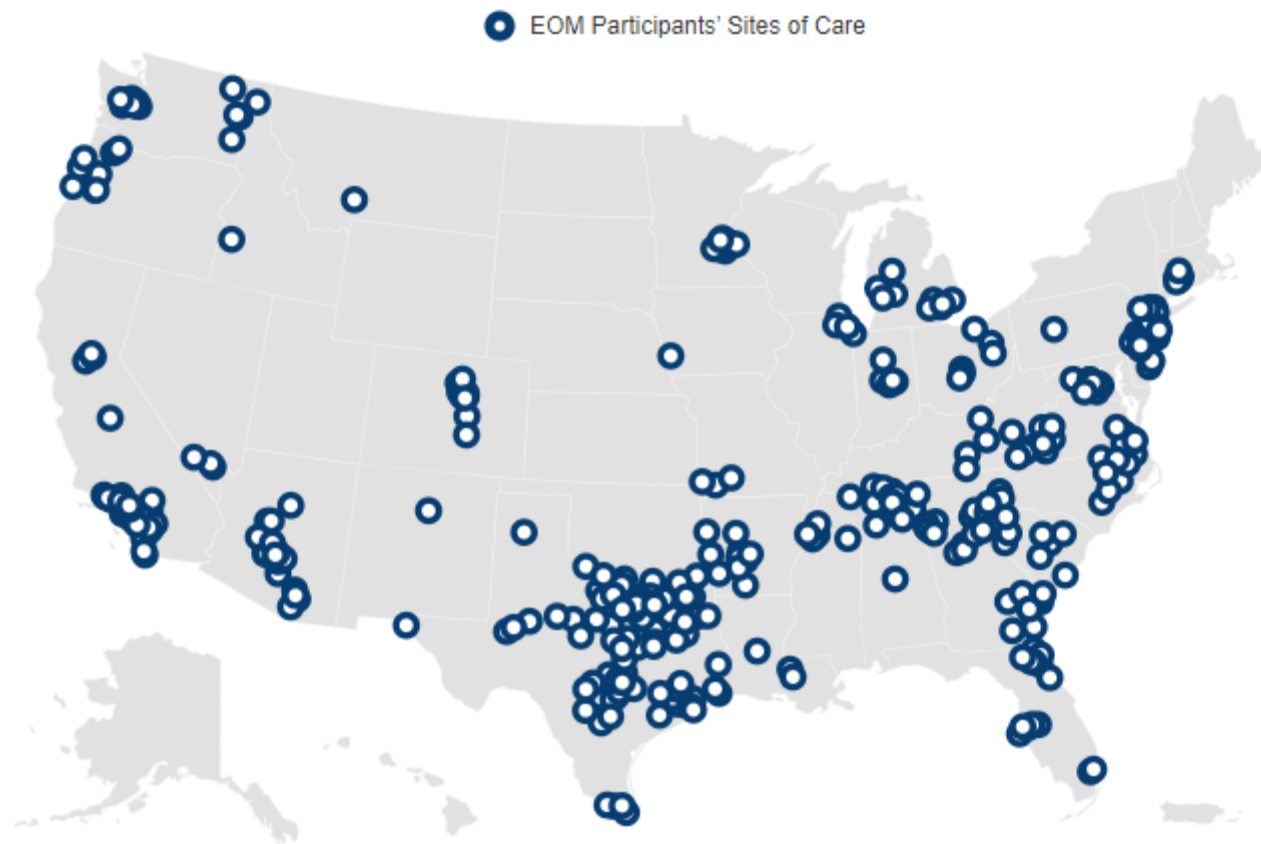
June 1, 2023

- Deadline: Participant agreements
- Provider Insight: “We had been told the deadline would be July 1st, so this is unfortunate”

July 1, 2023

- 5-year model begins with mandatory 2-sided risk on Day 1

# Participating Practices



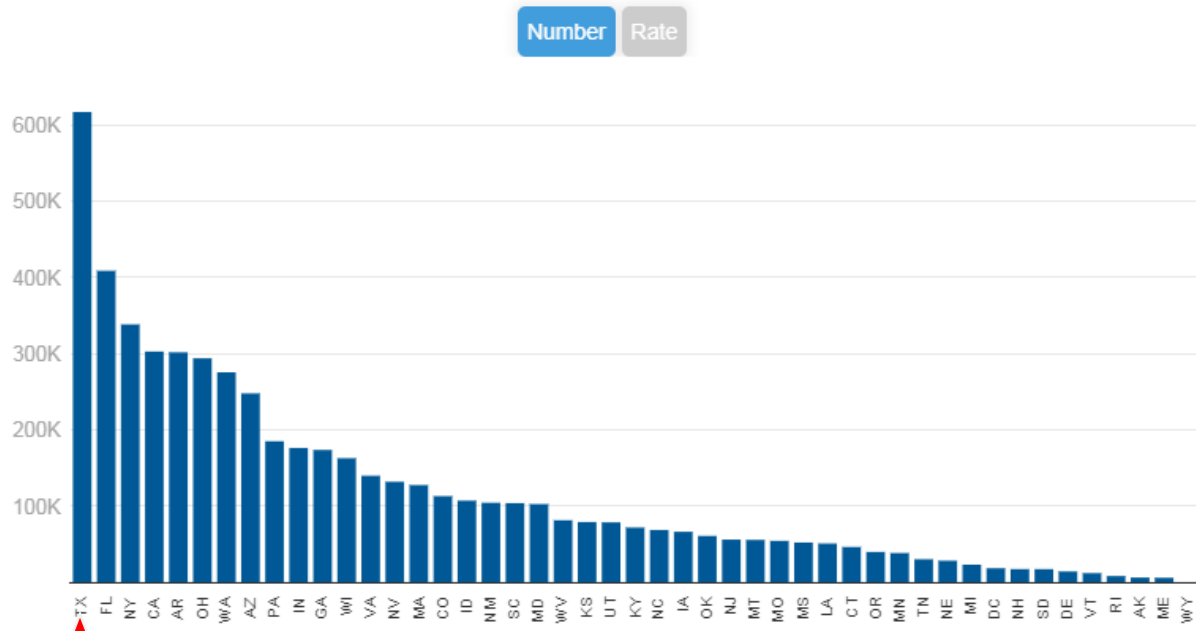
Source: Centers for Medicare & Medicaid Services

# Medicaid Unwinding: Updated Estimates

More than 5.4 million Medicaid enrollees have been disenrolled as of August 28, 2023, based on the most current data from 44 states and DC. There is wide variation in disenrollment rates across reporting states, which may in part be due to varying disenrollment strategies.

Figure 1  
At least 5,484,000 Medicaid enrollees have been disenrolled in 46 states and DC with publicly available unwinding data, as of August 28, 2023

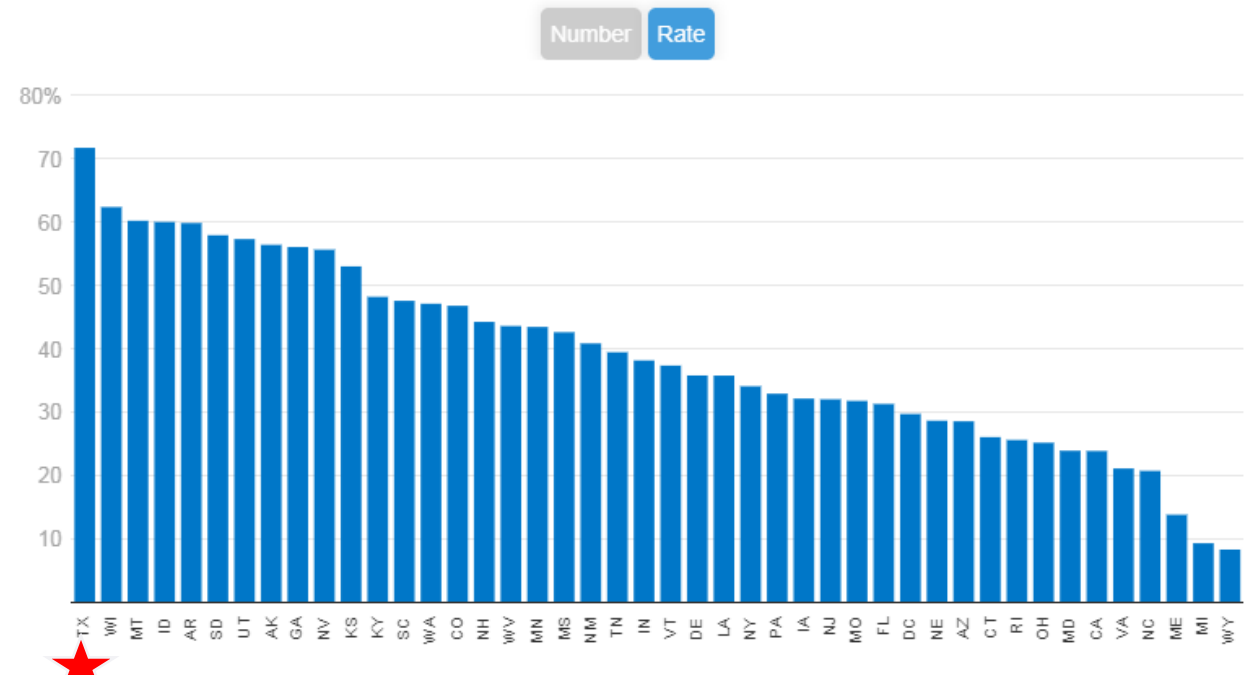
State-Reported Medicaid Disenrollments:



NOTE: Based on the most recent state-reported unwinding data available. Time periods differ by state.  
SOURCE: KFF Analysis of State Unwinding Dashboards and Monthly Reports Submitted to CMS • [Get the data](#) • PNG

Figure 1  
There is wide variation in disenrollment rates across reporting states, ranging from 72% in Texas to 8% in Wyoming

State-Reported Medicaid Disenrollments as a Share of Total Completed Renewals:



NOTE: Based on the most recent state-reported unwinding data available. Time periods differ by state. Rates are calculated as total disenrollments divided by total completed renewals (number whose coverage was renewed + number disenrolled); pending renewals are excluded. Several states report unwinding data on renewals without enough information to calculate a disenrollment rate.  
SOURCE: KFF Analysis of State Unwinding Dashboards and Monthly Reports Submitted to CMS • [Get the data](#) • PNG

# Stark Law & In-Office Dispensing: Mail-Order Prescriptions at Risk

March 2020:

- 3/30: CMS issued blanket [waivers](#) of sanctions under the physician self-referral law for COVID-19 Purposes.



Sept. 2021:

- CMS issued an [FAQ](#) related to the blanket waivers that suggests **mail-order prescription drugs** could violate the Stark Law once the waivers expire (when the PHE ends).
- COA believes that CMS' interpretation could also be used to prohibit a spouse or any caregiver from picking up a patient's drug(s) from the patient's medical practice.



May 2023:

- 5/11: PHE ends, along with the blanket waivers.
- 5/19: CMS issued an [FAQ](#) reiterating their position that **mail-order prescription drugs** violate the Stark law given that the PHE waivers have expired.
  - CMS stated that this is their "long-standing" position and that they do not anticipate harms to patient access (but will be monitoring).
  - CMS also noted that any changes would need to occur through notice and comment rulemaking.

## What can practices do when the blanket waivers expire?

- Utilize the VBE exception if practical
- Require patients to pick up medications in person or
- Refer them to third-party mail-order pharmacies

## Value-Based Enterprise (VBE) Exception

- There is a Value-Based Enterprise (VBE) exception that may provide a Stark Law exception for practices that mail medications, so long as they meet applicable criteria.
- The exception requires practices to be in an arrangement with full financial downside risk, partial downside risk, or no downside risk but engaging in value-based activities.
  - Practices not already engaged in a value-based arrangement may need to substantially alter their business practices to do so.

## References

[COA letter to HHS](#) (April 4, 2023)

[OBR article](#) (May 8, 2023)

[Congressional sign-on letter](#) from bipartisan group of 54 members to HHS urging CMS to retract the FAQ language (April 8, 2023)



# In-Office Dispensers & Mail Ship Update: COA Lawsuit



Filed 07/26/23

## Breaking News: COA Files Lawsuit Against HHS FAQ Limiting Cancer Drug Delivery to Patients

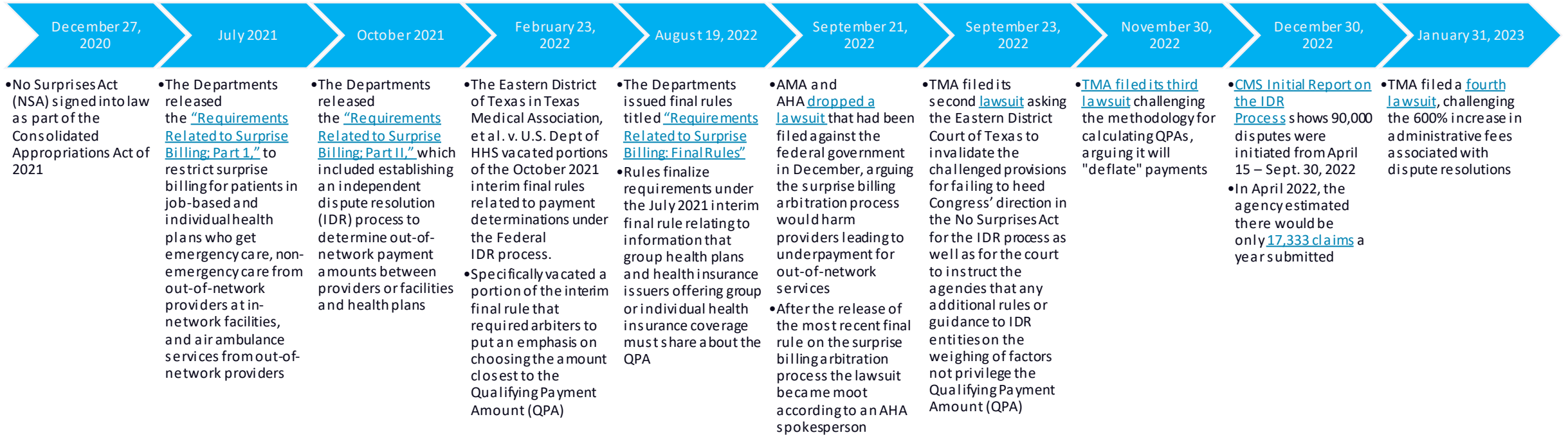
### Policy Change Restricting Practice Delivery of Oral Medications is Dangerous Display of Government Overreach, Says COA Suit

The Community Oncology Alliance (COA) has filed a lawsuit on behalf of its members and the patients they serve against the United States Department of Health and Human Services (HHS) to overturn a recent change in federal health policy restricting cancer practices from delivering drugs to patients. The suit calls the change in policy an unconstitutional and dangerous display of government overreach that presents real and irreparable injury to patients.

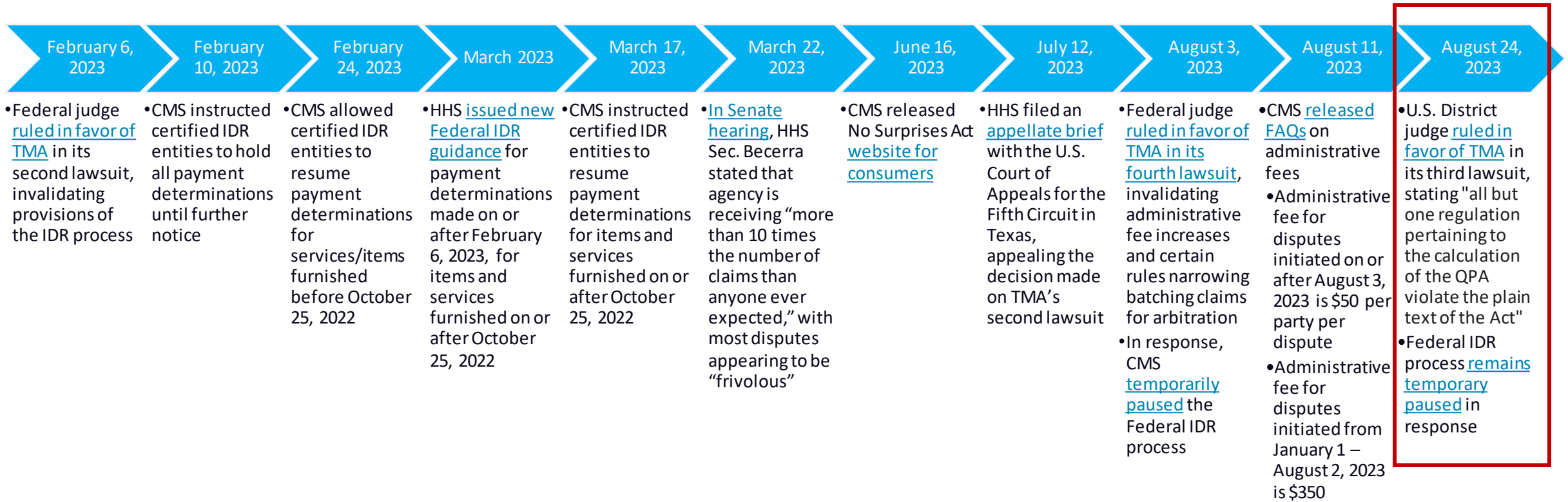
- [Click here to read the full lawsuit against the HHS drug delivery limits.](https://mycoa.s3.amazonaws.com/COA_StarkDrugDelivery_HHS-CMS_Lawsuit.pdf)



# No Surprises Act: Timeline



# No Surprises Act: Timeline



# CMS Announces First Ten Drugs Selected for Negotiation



On August 29, CMS announced the first ten Part D drugs selected for government negotiation

- The notable exclusions of Humira, Revlimid, and Lantus suggest that CMS is taking a more lenient approach to bona fide marketing
- The MFP for these drugs will be announced no later than September 1, 2024, and will take effect **January 1, 2026**

**Eliquis**  
(apixaban) tablets

1. Eliquis  
BMS

**Jardiance**  
(empagliflozin) tablets  
10 mg/25 mg

2. Jardiance  
Boehringer Ingelheim

**Xarelto**  
rivaroxaban  
tablets & oral suspension

3. Xarelto  
Janssen

**Januvia**  
(sitagliptin)  
25mg, 50mg, 100mg tablets

4. Januvia  
Merck

**farxiga**  
(dapagliflozin) 5mg & 10mg tablets

5. Farxiga  
AstraZeneca

**Entresto**  
sacubitril/valsartan

6. Entresto  
Novartis

**Enbrel**  
etanercept

7. Enbrel  
Amgen

**Imbruvica**  
(ibrutinib)  
420, 280, 140 mg tablets | 140, 70 mg capsules  
70 mg/mL oral suspension

8. Imbruvica  
AbbVie

**Stelara**  
(ustekinumab)

9. Stelara  
Janssen

**NovoLog**  
insulin aspart injection 100 Units/mL

10. Novolog  
Novo Nordisk

## TxSCO Takeaway

- Reimbursement for **Part B drugs** – as well as **commercial physician administered drugs** – will not be affected until **2028** price applicability year.
  - COA and other provider groups working on legislation to ensure provider reimbursement not impacted
- For now: Targeted Part D drugs, like Imbruvica, face new patient access concerns as plans might restrict access of negotiated products (due to manufacturers no longer being able to provide steep rebates).
  - According to ADVI's payer advisors, these access restrictions may kick in before 2026

# State Update

# Session Update – Bill Highlights

## Passed Bills

### **SB 773 - Parker: Relating to access to certain investigational drugs, biological products, and devices used in clinical trials by patients with severe chronic diseases.**

- Provides patients with severe chronic conditions, as determined by HHSC, **access to investigational treatments** that have passed Phase 1 clinical trials in certain circumstances with physician determination that other treatments are unlikely to provide relief or are unavailable.

### **HB 12 - Rose: Relating to the duration of services provided under Medicaid to women following a pregnancy.**

- Allows  **moms to continue using their Medicaid** health insurance for a full year after pregnancy.

### **HB 44 - Swanson: Relating to provider discrimination against a Medicaid recipient or child health plan program enrollee based on immunization status.**

- Removes state health funding, including Medicaid and CHIP funding, if a health provider declines to serve a potential patient because of refusal or failure to obtain certain immunizations or **vaccines**. Still allows providers to require immunization as long as the provider allows for certain exemptions. Does not apply to providers who specialize in oncology or organ transplant.

### **HB 999 - Price: Relating to the effect of certain reductions in a health benefit plan enrollee's out-of-pocket expenses for certain prescription drugs on enrollee cost-sharing requirements.**

- Prohibits the use of **copay accumulator** programs in most instances.

### **HB 1647 - Harris, Cody: Relating to health benefit plan coverage of clinician-administered drugs.**

- Prohibits **whitebagging** mandates for clinician administered drugs in a physician office setting.

### **HB 1649 - Chen Button: Relating to health benefit coverage for certain fertility preservation services under certain health benefit plans.**

- Provides for mandated health plan **coverage of fertility preservation** services but does not include the storage of unfertilized eggs. Also includes a notice requirement for facilities who provide chemotherapy radiation procedures to notify parents that the procedure could impair the fertility of their child.

### **SB 989 - Huffman: Relating to health benefit plan coverage for certain biomarker testing.**

- Provides required coverage for certain **biomarker** testing that provides clinical utility.

### **SB 25 - Kolkhorst: Relating to support for nursing-related postsecondary education, including scholarships to nursing students, loan repayment assistance to nurses and nursing faculty, and grants to nursing education programs.**

- Expands the current **nursing loan repayment program** to nurses working part time, allows the THECB to increase the existing \$7,000 annual cap per nurse and reestablishes the program until 2027.

### **SB 401 - Kolkhorst: Relating to prices charged by medical staffing services agency during a declared state of disaster.**

- Prohibits **medical staffing agencies** from charging exorbitant or excessive prices during a declared state of disaster.

### **HB 25 - Talarico: Relating to wholesale importation of prescription drugs in this state; authorizing a fee.**

- Directs the state to develop a **Canadian importation** program to be approved by the federal government.

# Session Update – Bill Highlights

## Defeated Bills

### **HB 536 - Wu: Relating to liability limits in a health care liability claim.**

- Would have tied liability limits for health care liability claims to the consumer price index (CPI).

### **HB 1240 - Oliverson: Relating to the authority of a physician to provide and dispense and to delegate authority to provide and dispense certain drugs.**

- Would have authorized a physician to provide or dispense drugs to the physician's patients and be reimbursed for the cost of providing or dispensing those drugs without obtaining a license to practice.

### **HB 2587 - Howard: Relating to eligibility for Medicaid for breast and cervical cancer.**

- Would have expanded the BCCS program to women at or below 250% FPL.

### **HB 118 - Cortez: Relating to health benefit plan coverage for certain tests to detect prostate cancer.**

- Would have prevented health plans from charging a premium, copayment, deductible, or other form of cost sharing for prostate cancer screening.

### **HB 2414 - Frank: Relating to the relationship between a physician or health care provider and a health maintenance organization or insurer.**

- Would have allowed health insurers to incentivize the use of affiliated providers as long as they maintain a fiduciary responsibility to their patient.

### **SB 1137 - Schwertner: Relating to applicability of certain insurance laws to pharmacy benefit managers.**

- Would have expanded the patient and provider protections passed last session, specifically HB 1919 and HB 1763 to ERISA plans

### **SB 1581 - Bettencourt: Relating to the establishment of the Texas Health Insurance Mandate Advisory Committee.**

- Would have established the Texas Health Insurance Mandate Advisory Committee to study and make recommendations related to required health plan benefits.

### **HB 826 - Lambert: Relating to modification of certain prescription drug benefits and coverage offered by certain health benefit plans.**

- Would have prohibited non-medical switching and other changes to drug coverage within a plan year with certain exceptions.

# Session Update – Budget Highlights

- The Texas Legislature made broad investments to increase the healthcare workforce through existing programs:
  - an increase of \$6 million for a total of almost \$80 million total for the Physician Education Loan Repayment Program
  - An increase of \$7 million for a total of \$16.5 million for the Family Practice Residency Program
  - An increase of \$34 million, for a total of \$233.1 million, for Graduate Medical Education slots
  - Increases the Nurse Faculty Loan Repayment Program by \$4.1million for a total of \$7 million
  - An increase of \$27.9 million for the Professional Nursing Shortage Program, for a total of \$46.8 million
  - \$25 million for nursing scholarships
  - \$6 million for a Nursing Innovation Grant Program
  - A requirement for the Texas Higher Education Coordinating Board to develop a report on social work workforce and the state's needs



# Session Update – Budget Highlights

- The Texas Colorectal Cancer Initiative, a new program developed with the leadership of David Lakey, M.D., with the University of Texas System, was funded with \$10 million for the treatment of colorectal cancer for uninsured and underinsured Texas residents at or below 200 percent of the federal poverty level.
- A 6% increase for reimbursement rates for women's health related surgeries
- Includes \$447.2 million in All Funds for women's health programs, an increase of \$160.1 million over current spending
- \$10 million is appropriated to the Department of State Health Services to increase the number of Women's Preventative Health Mobile Units



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