



Federal & State Policy Updates

TxSCO

Sept. 23, 2023

Federal Updates

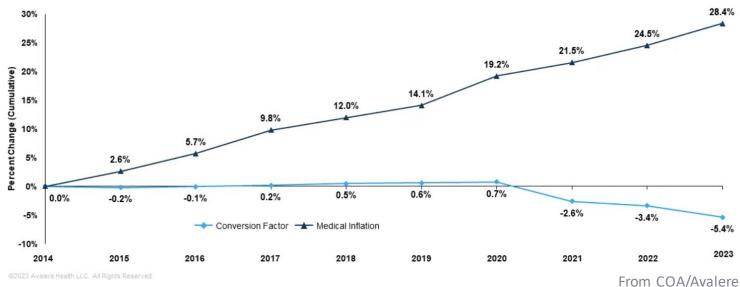
Key Federal Policy Issues

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

- 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:
- 13 other Specialties: -2%

CPI-U Medical v. Conversion Factor



Enhancing Oncology Model (EOM)

Oct. 2022

 Nonbinding application s due (nonbinding) 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



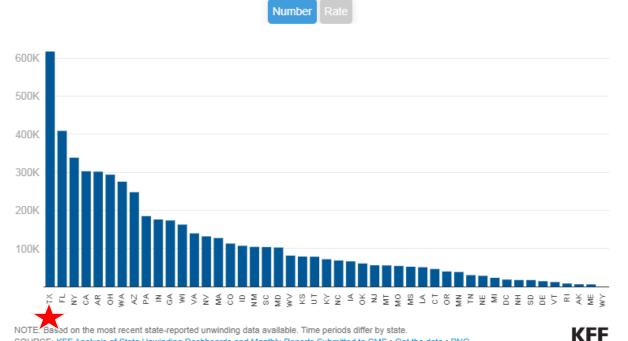
Medicaid Unwinding: Updated Estimates

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:

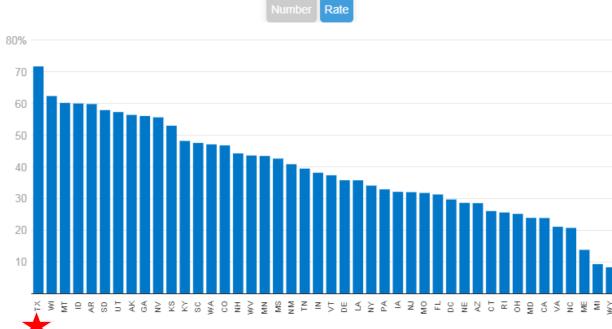


SOURCE: KFF Analysis of State Unwinding Dashboards and Monthly Reports Submitted to CMS • Get the data • PNG

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

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Source: KFF (8/28/23, link)

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

March 2020:

• 3/30: CMS issued blanket <u>waivers</u> of sanctions under the physician self-referral law for COVID-19 Purposes.

Sept. 2021:

- CMS issued an <u>FAQ</u> related to the blanket waivers that suggests <u>mail-order</u>
 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 <u>FAQ</u> 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.

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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.

UNITED STATES DISTRICT COURT DISTRICT OF COLUMBIA		
COMMUNITY ONCOLOGY ALLIANCE,	Girl Action No.:	
Plaintiff,	Hos	USDJ.
-against-	Hon.	USMJ.
XAVIER BECERRA, Secretary of U.S. Department of Health and Human Services,	VERIFIED COMPLAINT	
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,		
CHIQUITA BROOKS-LASURE, Administrator of the Genters for Medicare and Medicaid Services,		
CENTERS FOR MEDICARE AND MEDICAID SERVICES,		
Defendants.		
Plaintiff, Community Oncology Alliance ("COA" or "Plaintiff"), individually and on behalf of its organizational members comprised of community oncology practices throughout the United States,		
by and through its undersigned counsel, hereby make the following allegations against Defendants,		
Xerior Becoms ("Becoms") as Socretary of the United States Department of Health and Human		
Services, the United States Department of Health and Human Services ("HERS"), Chiquita Brooks-		

No Surprises Act: Timeline



December 27.

October 2021

2022

August 19, 2022

September 21.

September 23.

November 30.

December 30. 2022

January 31, 2023

- No Surprises Act (NSA) signed into law released as part of the Consolidated Appropriations Act of 2021
- •The Departments the "Requirements Related to Surprise Billing; Part 1," to restrict surprise billing for patients in iob-based and individual health plans who get emergency care, non-network payment emergency care from out-of-network providers at innetwork facilities, and air ambulance services from out-ofnetwork providers

July 2021

- •The Departments released the "Requirements Related to Surprise Billing: Part II." which included establishing an independent dispute resolution (IDR) process to determine out-ofamounts between providers or facilities and health plans
- The Eastern District of Texas in Texas Medical Association. et al. v. U.S. Dept of HHS vacated portions of the October 2021 interim final rules related to payment determinations under the Federal IDR process.
 - •Specifically vacated a and health insurance portion of the interim final rule that required arbiters to put an emphasis on choosing the amount QPA clos est to the Qualifying Payment Amount (QPA)

- •The Departments issued final rules titled "Requirements Related to Surprise Billing: Final Rules"
- •Rules finalize requirements under the July 2021 interim final rule relating to information that group health plans is suers offering group or individual health insurance coverage must share about the
- AMA and AHA <u>dropped a</u> lawsuit that had been the Eastern District filed against the federal government in December, arguing the surprise billing arbitration process wouldharm providers leading to underpayment for out-of-network s e rvi ces
 - After the release of the most recent final rule on the surprise billingarbitration process the lawsuit became moot according to an AHA spokesperson
- •TMA filed its second lawsuit asking Court of Texas to invalidate the challenged provisions for failing to heed Congress' direction in the No Surprises Act for the IDR process as well as for the court to instruct the agencies that any additional rules or guidance to IDR entities on the weighing of factors not privilege the Qualifying Payment Amount (QPA)
 - •TMA filed its third <u>lawsuit</u> challenging the IDR the methodology for Process shows 90,000 calculating QPAs, disputes were arguing it will initiated from April

"deflate" payments

•In April 2022, the agencyestimated there would be only 17.333 claims a vearsubmitted

15 - Sept. 30, 2022

•CMS Initial Report on •TMA filed a fourth lawsuit, challenging the 600% increase in administrative fees associated with dispute resolutions

No Surprises Act: Timeline



August 24, February 6, **February** February March 17, March 22, June 16, July 12, August 3, August 11, March 2023 2023 10, 2023 24, 2023 2023 2023 2023 2023 2023 2023 2023 CMS allowed •HHS issued new •CMS instructed •CMS released •HHS filed an •U.S. District Federal judge CMS instructed In Senate Federal judge CMS released ruled in favor of certified IDR certified IDR Federal IDR certified IDR No Surprises Act appellate brief ruled in favor of FAQs on judge ruled in hearing, HHS entities to hold entities to guidance for entities to Sec. Becerra website for with the U.S. TMA in its administrative favor of TMA in TMA in its second lawsuit, all payment stated that Court of fourth lawsuit, fees its third lawsuit, resume payment resume consumers invalidating determinations Appeals for the invalidating stating "all but payment determinations payment agency is Administrative until further receiving "more Fifth Circuit in provisions of determinations made on or determinations administrative one regulation fee for the IDR process notice after February for items and than 10 times for fee increases pertaining to Texas, disputes services/items 6, 2023, for appealing the and certain the calculation services the number of initiated on or furnished items and furnished on or claims than decision made rules narrowing of the QPA after August 3, after October batching claims before October services anvone ever on TMA's violate the plain 2023 is \$50 per 25, 2022 25, 2022 expected," with furnished on or second lawsuit for arbitration text of the Act" party per after October most disputes Federal IDR •In response, dispute 25, 2022 appearing to be CMS process remains Administrative "frivolous" temporarily temporary fee for paused the paused in disputes Federal IDR initiated from response process January 1 -August 2, 2023 is \$350

CMS: No Surprises Act website

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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





















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

- 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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