TxSCO Update

September 14, 2023

Overview: Notable Updates

Federal

- First 10 drugs selected for IRA negotiation
- No Surprises Act
- Medicaid unwinding
- Comments on the PFS Proposed Rule

State

- AG Impeachment Trial Update
- Upcoming Special Session
- Legislative Retirements

Federal Updates

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TxSCO Takeaway: Part B drugs (and Part B/commercial drug reimbursement) will not be affected until 2028 price applicability year.
For the following Part D drugs, new patient access concerns as plans might restrict access of negotiated products (due to manufacturers no longer being able to provide steep rebates).

CMS Announces First Ten Drugs Selected for Negotiation

MEDICARE DRUG PRICE NEGOTIATION PROGRAM
CENTERS FOR MEDICARE & MEDICAID SERVICES

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

1. Eliquis (apixaban) tablets — BMS
2. Jardiance (empagliflozin) tablets 10 mg/25 mg — Boehringer Ingelheim
3. Xarelto rivaroxaban tablets & oral suspension — Janssen
4. Januvia (sitagliptin) 25 mg, 50 mg, 100 mg tablets — Merck
5. Farxiga (dapagliflozin) 5 mg & 10 mg tablets — AstraZeneca
6. Entresto sacubitril/valsartan — Novartis
7. Enbrel etanercept — Amgen
8. Imbruvica (ibrutinib) 420, 280, 140 mg tablets | 140, 70 mg capsules 70 mg/mL oral suspension — AbbVie
9. Stelara (ustekinumab) — Janssen
10. NovoLog insulin aspart injection 100 Units/mL — Novo Nordisk

Next Steps in 2023

August 29
Selected drugs announced

September 1 – October 2
Members of the public may apply to speak at the patient-focused listening sessions

October 1
Deadline to sign negotiation agreements

October 2
Manufacturer-specific data & TA submissions due

October 30 – November 15
CMS holds patient-focused listening sessions

Fall 2023
First CMS-Manufacturer meetings held

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CMS Announces First Ten Drugs Selected for Negotiation

Drug	Manufacturer	Indication	Total Part D Gross Cost June '22-May '23	Part D Enrollees Using Drug June '22-May '23
Eliquis	BMS	Prevention/Treatment Blood Clots	$16,482,621,000	3,706,000
Jardiance	Boehringer Ingelheim	Diabetes; Heart Failure	$7,057,707,000	1,573,000
Xarelto	Bayer	Prevention/Treatment Blood Clots; Risk Reduction coronary/pulmonary artery disease	$6,031,393,000	1,337,000
Januvia	Merck	Diabetes	$4,087,081,000	869,000
Farxiga	AstraZeneca	Diabetes; Heart Failure; CKD	$3,268,329,000	799,000
Entresto	Novartis	Heart Failure	$2,844,877,000	587,000
Enbrel	Amgen	RA; Psoriasis; Psoriatic Arthritis	$2,791,105,000	48,000
Imbruvica	AbbVie & Janssen	Blood Cancers	$2,663,560,000	20,000
Stelara	Janssen	Psoriasis; Psoriatic Arthritis; Chrone's; UC	$2,638,929,000	22,000
Fiasp; Fiasp FlexTouch, Fiasp PenFill; NovoLog; FlexPen; NovoLog PenFill	Novo Nordisk	Diabetes	$2,576,586,000	777,000

"This plan is a key part of Bidenomics, my economic vision for growing the economy from the middle out and the bottom up – not the top down. And it's working. That's why Big Pharma has already filed eight lawsuits against my Administration, and spent nearly $400 million last year to try to stop our progress. Let me be clear: I am not backing down."

-President Joe Biden

"Medicare patients who are prescribed ELIQUIS are currently able to get it with relatively low out-of-pocket costs at an average of $55 per month. This reality is at risk, as the government has not required that insurance companies make selected medicines available in the future without burdensome cost sharing or hurdles to access."

-BMS

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No Surprises Act: Timeline

December 27, 2020	July 2021	October 2021	February 23, 2022	August 19, 2022	September 21, 2022	September 23, 2022	November 30, 2022	December 30, 2022	January 31, 2023
•No Surprises Act (NSA) signed into law as part of the Consolidated Appropriations Act of 2021	•The Departments released the "Requirements Related to Surprise Billing; Part 1," to restrict surprise billing for patients in job-based and individual health plans who get emergency care, non-emergency care from out-of-network providers at in-network facilities, and air ambulance services from out-of-network providers	•The Departments released the "Requirements Related to Surprise Billing; Part II," which included establishing an independent dispute resolution (IDR) process to determine out-of-network payment amounts 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 portion of the interim final rule that required arbiters to put an emphasis on choosing the amount closest 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 and health insurance issuers offering group or individual health insurance coverage must share about the QPA	•AMA and AHA dropped a lawsuit that had been filed against the federal government in December, arguing the surprise billing arbitration process would harm providers leading to underpayment for out-of-network services •After the release of the most recent final rule on the surprise billing arbitration process the lawsuit became moot according to an AHA spokesperson	•TMA filed its second lawsuit asking the Eastern District 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 lawsuit challenging the methodology for calculating QPAs, arguing it will "deflate" payments	•CMS Initial Report on the IDR Process shows 90,000 disputes were initiated from April 15 – Sept. 30, 2022 •In April 2022, the agency estimated there would be only 17,333 claims a year submitted	•TMA filed a fourth lawsuit, challenging the 600% increase in administrative fees associated with dispute resolutions

CMS: No Surprises Act website

No Surprises Act: Timeline

February 6, 2023

- Federal judge ruled in favor of TMA in its second lawsuit, invalidating provisions of the IDR process

February 10, 2023

- CMS instructed certified IDR entities to hold all payment determinations until further notice

February 24, 2023

- CMS allowed certified IDR entities to resume payment determinations for services/items furnished before October 25, 2022

March 2023

- HHS issued new Federal IDR guidance for payment determinations made on or after February 6, 2023, for items and services furnished on or after October 25, 2022

March 17, 2023

- CMS instructed certified IDR entities to resume payment determinations for items and services furnished on or after October 25, 2022

March 22, 2023

- In Senate hearing, HHS Sec. Becerra stated that agency is receiving "more than 10 times the number of claims than anyone ever expected," with most disputes appearing to be "frivolous"

June 16, 2023

- CMS released No Surprises Act website for consumers

July 12, 2023

- HHS filed an appellate brief with the U.S. Court of Appeals for the Fifth Circuit in Texas, appealing the decision made on TMA's second lawsuit

August 3, 2023

- Federal judge ruled in favor of TMA in its fourth lawsuit, invalidating administrative fee increases and certain rules narrowing batching claims for arbitration
- In response, CMS temporarily paused the Federal IDR process

August 11, 2023

- CMS released FAQs on administrative fees
  - Administrative fee for disputes initiated on or after August 3, 2023 is $50 per party per dispute
  - Administrative fee for disputes initiated from January 1 – August 2, 2023 is $350

August 24, 2023

- U.S. District judge ruled in favor of TMA in its third lawsuit, stating "all but one regulation pertaining to the calculation of the QPA violate the plain text of the Act"
- Federal IDR process remains temporary paused in response

CMS: No Surprises Act website

Provider Groups Warn Against Proposed PFS Rate Decrease in Comment Letters

Conversion Factor

- "The AHA considers the proposed conversion factor update woefully inadequate considering the declines in physician reimbursement over the last few decades."
- "The AMA again questions the wisdom of the conversion factor reductions, specifically the proposed 3.36 percent reduction in 2024."
- "…it is unrealistic to expect providers to meet the increasing demand for Medicare services if reimbursement rates continue to drop and costs continue to rise." – AMGA
- "The cuts stemming from the 3.36% decrease to the CY 2024 conversion factor paired with the current inflationary environment are simply unsustainable. In an MGMA poll conducted in August 2023, 95% of medical practices reported that the projected reduction to 2024 Medicare payment would negatively impact their ability to deliver timely, high-quality care to patients." – MGMA
- "NAACOS is concerned that continual cuts create a disincentive for clinicians to adopt population health models."

E/M Code G2211 Implementation

- "While we directionally support adjustments to reimbursement to account for clinical complexity, we are concerned about the redistributive impact of this particular code and impact on the conversion factor in outyears." – AHA
- "…we must strongly echo the concerns raised by various stakeholders regarding the utilization assumptions for G2211, which are driving nearly all of the 2024 budget neutrality reduction…" – AMA
- "AMGA is concerned the add-on code (G2211) will lead to additional across-the-board cuts, which illustrate the flaws inherent to the physician fee schedule's budget neutrality requirements."

MIPS

- "The AMA is concerned about CMS's proposal to raise the performance threshold to 82 points for the 2024 period…Estimations reveal that about 54 percent of MIPS eligible clinicians might face penalties averaging 2.4 percent if the proposed 82-point threshold is implemented."
- "Do not finalize the proposal to increase the MIPS performance threshold…CMS should revise its methodology to avoid this untenable increase…The agency's own estimates suggest that over half of MIPS eligible clinicians should be penalized." – MGMA

Source: AHA comment letter (link); AMA comment letter (link); AMGA comment letter (link); MGMA comment letter (link); NAACOS comment letter (link)

Medicaid Unwinding

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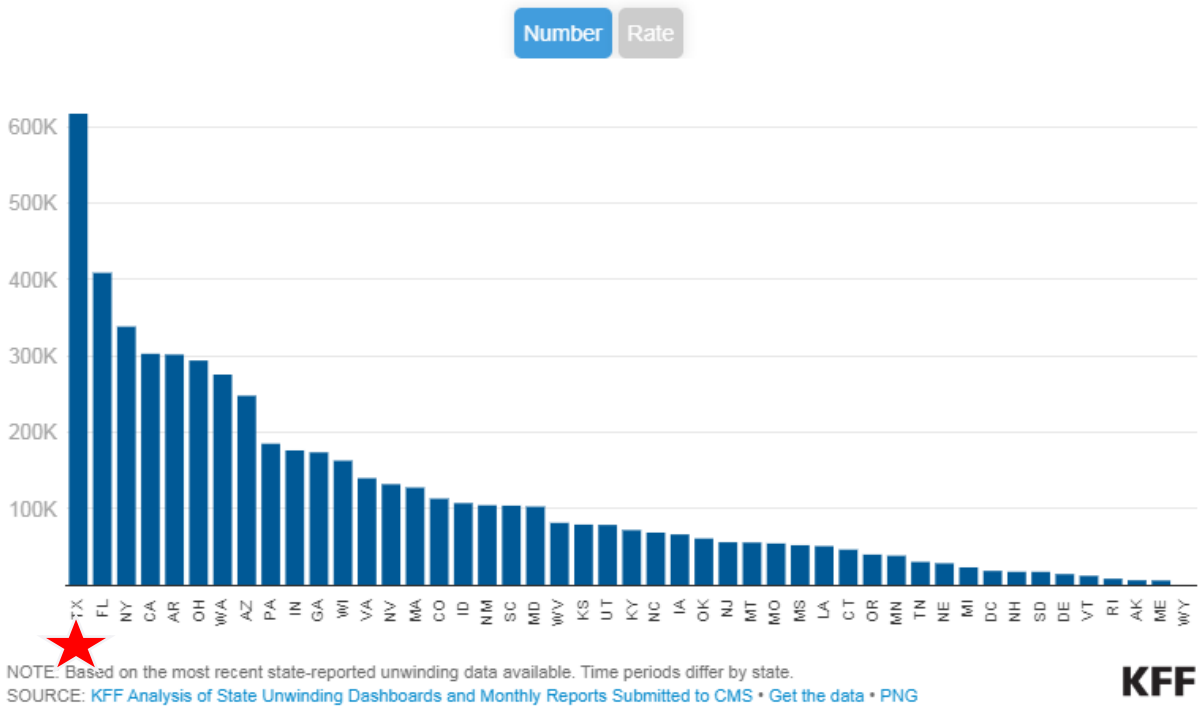
Medicaid Unwinding: Updated Estimates

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:



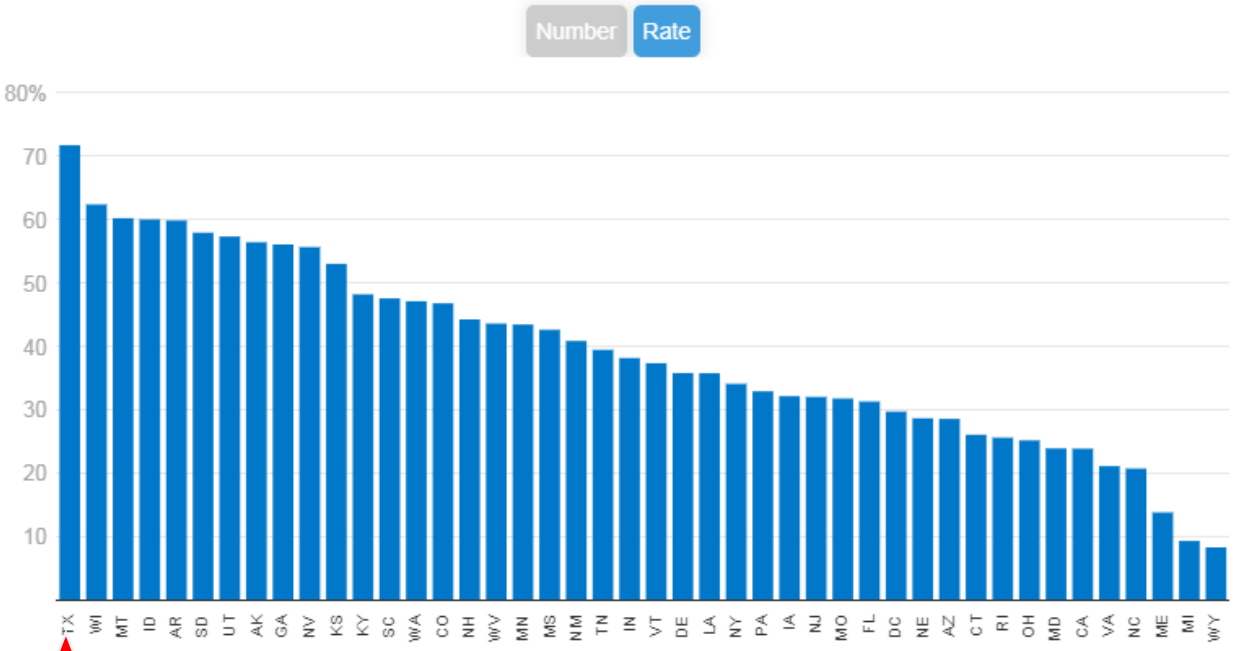
NOTE: Based on the most recent state-reported unwinding data available. Time periods differ by state.
SOURCE: KFF Analysis of State Unwinding Dashboards and Monthly Reports Submitted to CMS • Get the data • PNG

KFF

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

KFF

ADVI

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

KFF

Medicaid Unwinding: Updated Estimates

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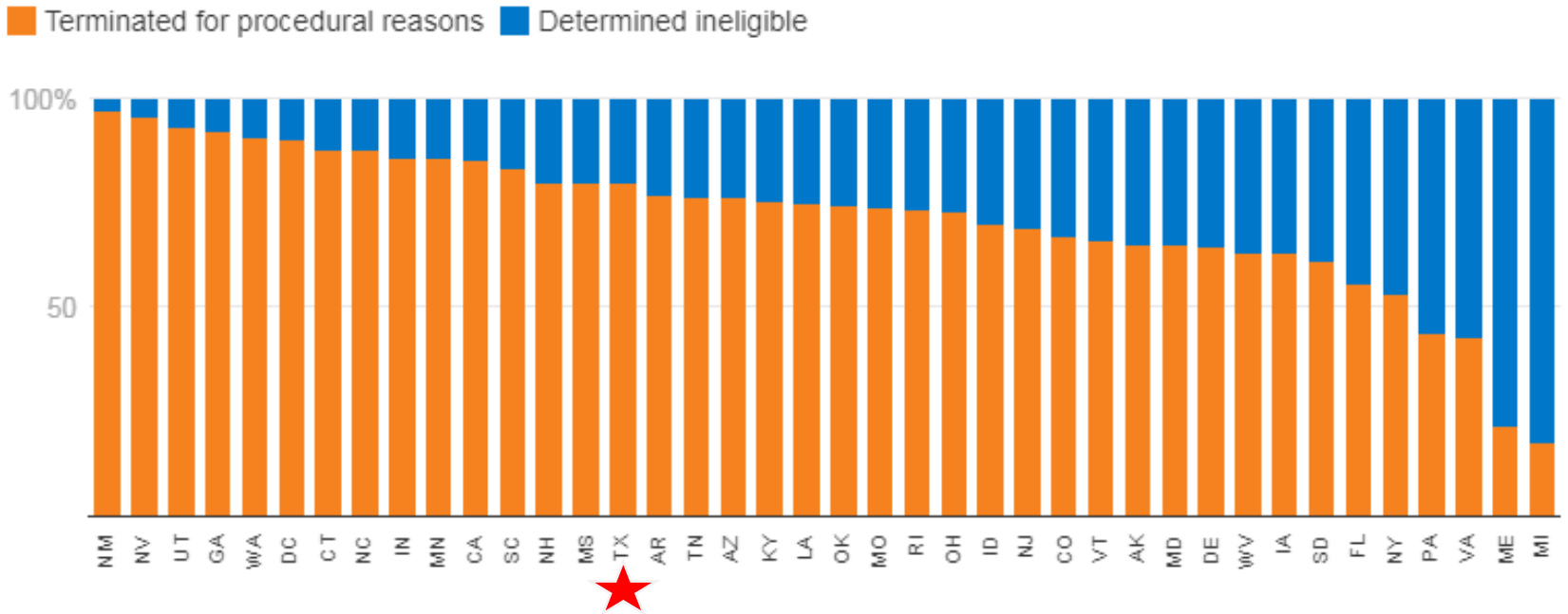
Figure 2

Overall, 74% of disenrollments are due to procedural reasons, among states reporting as of August 28, 2023

Of Total Disenrollments, the Share Disenrolled for Procedural Reasons vs. the Share Determined Ineligible:



NOTE: Procedural disenrollments occur when the state cannot verify an individual's ongoing eligibility at renewal. Based on the most recent state-reported unwinding data available. Time periods differ by state. Rates are calculated as procedural disenrollments divided by total disenrollments. Several states report unwinding data without information on reason for disenrollment and are not shown in this figure.

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)

CMS Warns States on Unwinding Compliance

August 9: CMS sends letters to all State Medicaid Directors identifying May 2023 performance in call center operations, terminations for procedural reasons, and application processing times.

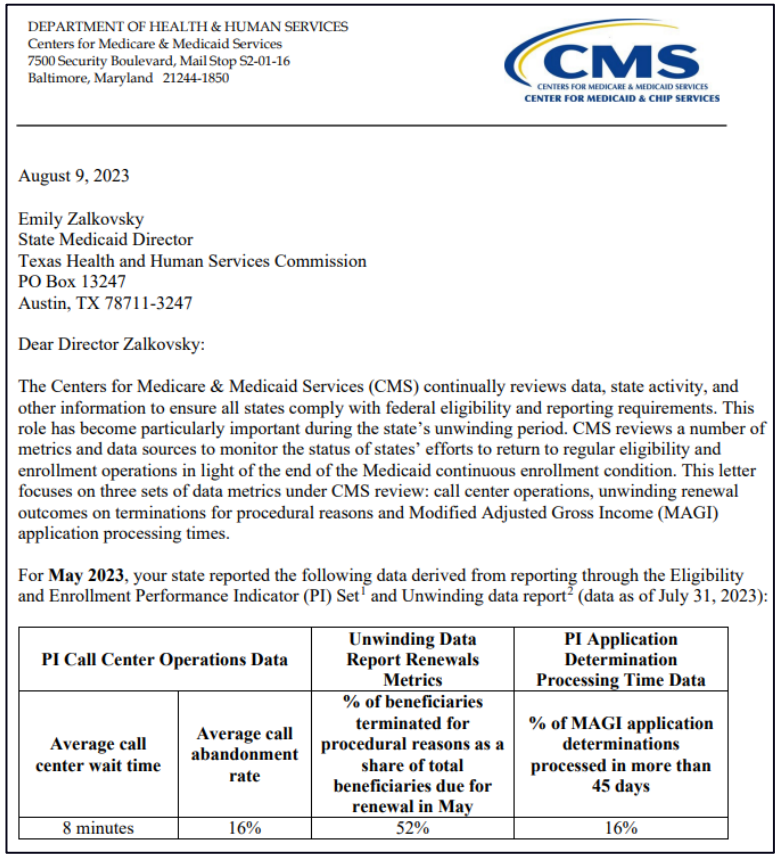
CMS Letter language described as a step "toward more punitive measures"

Call Center Operations: "Excessive call center wait times and call abandonment rates may indicate that the state is not meeting the requirements of providing a meaningful opportunity to complete an application or renewal for Medicaid and CHIP telephonically." CMS expects the wait times to be less than 10 minutes.

Terminations for Procedural Reasons: "While CMS expects procedural terminations, a high rate of procedural terminations may indicate that beneficiaries may not be receiving notices, are unable to understand them, or are unable to submit their renewal through the required modalities."

Application Processing Time: "The determination of eligibility for any individual may not exceed 90 days for applicants who apply on the basis of a disability and 45 days for all other applicants, including those whose eligibility is being determined based on their MAGI."

- MO had highest average call center wait time of 48 minutes
- NV had highest call center abandonment rate at 56%
- ID, NV, NH, SC, TX, UT, and WA removed over 40% of Medicaid enrollees for procedural reasons
- 36 states did not meet requirements in 1 area
- AK, FL, MT, NM, and RI did not meet any requirements



DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-01-16
Baltimore, Maryland 21244-1850

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICAID & CHIP SERVICES

August 9, 2023

Emily Zalkovsky
State Medicaid Director
Texas Health and Human Services Commission
PO Box 13247
Austin, TX 78711-3247

Dear Director Zalkovsky:

The Centers for Medicare & Medicaid Services (CMS) continually reviews data, state activity, and other information to ensure all states comply with federal eligibility and reporting requirements. This role has become particularly important during the state's unwinding period. CMS reviews a number of metrics and data sources to monitor the status of states' efforts to return to regular eligibility and enrollment operations in light of the end of the Medicaid continuous enrollment condition. This letter focuses on three sets of data metrics under CMS review: call center operations, unwinding renewal outcomes on terminations for procedural reasons and Modified Adjusted Gross Income (MAGI) application processing times.

For **May 2023**, your state reported the following data derived from reporting through the Eligibility and Enrollment Performance Indicator (PI) Set[1] and Unwinding data report[2] (data as of July 31, 2023):

PI Call Center Operations Data		Unwinding Data Report Renewals Metrics	PI Application Determination Processing Time Data
Average call center wait time	Average call abandonment rate	% of beneficiaries terminated for procedural reasons as a share of total beneficiaries due for renewal in May	% of MAGI application determinations processed in more than 45 days
8 minutes	16%	52%	16%

Source: CMS Letter to Texas Health and Human Services Commission (8/9/23, link); PoliticoPro: "Biden administration warns states as millions lose Medicaid" (8/10/23, link); IHP: "CMS: Seven States Dropped More than 40% Of Medicaid Benes In May" (8/11/23, link)

CMS Sent A Letter Requiring State Medicaid Programs Determine Eligibility Systems Issues

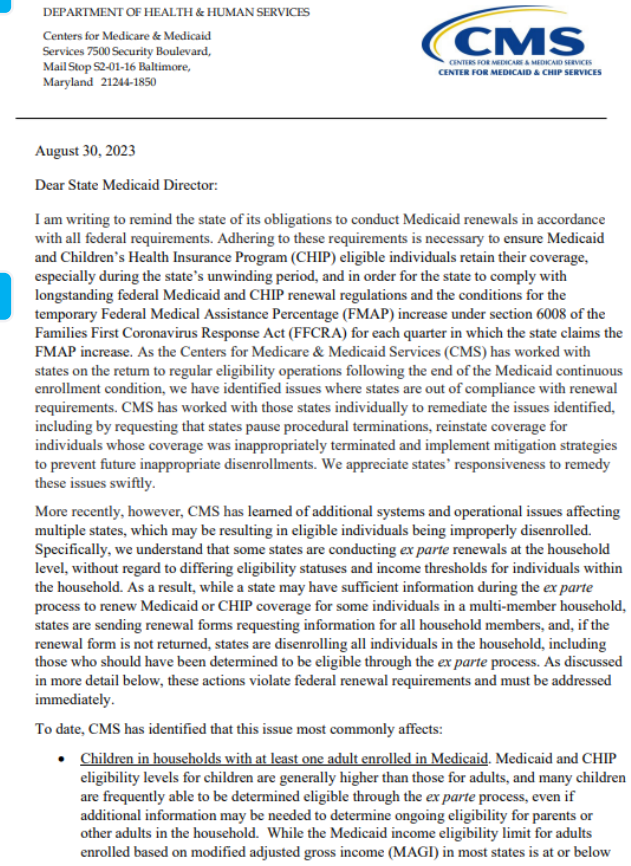
Ex Parte Renewals - Background

- On August 30, CMS sent a letter to all State Medicaid Programs mandating they determine and update eligibility systems issues by September 13.
- CMS previously found some states are conducing *ex parte* renewals at the household level without regard to differing eligibility statuses and income thresholds for individuals within the household.
  - States are sending renewal forms requesting information of all household members; if the form is not returned, states are disenrolling all individuals in the household.

Required State Action

- CMS is requiring all Medicaid and CHIP agencies to review their renewal processes. To do so, states must:

1. Pause procedural terminations for those individuals for whom the ex parte renewal process is not currently compliant.
2. Reinstate coverage for all affected individuals who have been procedurally disenrolled due to a failure to account for the individual's eligibility status, independent of that of others in the household.
   a) State must provide retroactive eligibility and notify affected individuals that their coverage has been reinstate and inform on any next steps.
3. Fix systems and processes to ensure that redeterminations are conducted appropriately for all household individuals.
4. Implement mitigation strategies to prevent continued inappropriate terminations until the state has fixed all systems and processes compliant with renewal requirements.
   a) Identify or renew eligibility for affected individuals prior to disenrollment for procedural reason.
   b) Suspend renewals for while the state implements needed systems and operational fixes.
   c) Waive the redetermination requirement and extend Medicaid or CHIP eligibility for impacted household members for up to 12 months from the member's scheduled renewal during unwinding period.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services 7500 Security Boulevard, Mail Stop S2-01-16 Baltimore, Maryland 21244-1850

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES CENTER FOR MEDICAID & CHIP SERVICES

August 30, 2023

Dear State Medicaid Director:

I am writing to remind the state of its obligations to conduct Medicaid renewals in accordance with all federal requirements. Adhering to these requirements is necessary to ensure Medicaid and Children's Health Insurance Program (CHIP) eligible individuals retain their coverage, especially during the state's unwinding period, and in order for the state to comply with longstanding federal Medicaid and CHIP renewal regulations and the conditions for the temporary Federal Medical Assistance Percentage (FMAP) increase under section 6008 of the Families First Coronavirus Response Act (FFCRA) for each quarter in which the state claims the FMAP increase. As the Centers for Medicare & Medicaid Services (CMS) has worked with states on the return to regular eligibility operations following the end of the Medicaid continuous enrollment condition, we have identified issues where states are out of compliance with renewal requirements. CMS has worked with those states individually to remediate the issues identified, including by requesting that states pause procedural terminations, reinstate coverage for individuals whose coverage was inappropriately terminated and implement mitigation strategies to prevent future inappropriate disenrollments. We appreciate states' responsiveness to remedy these issues swiftly.

More recently, however, CMS has learned of additional systems and operational issues affecting multiple states, which may be resulting in eligible individuals being improperly disenrolled. Specifically, we understand that some states are conducting *ex parte* renewals at the household level, without regard to differing eligibility statuses and income thresholds for individuals within the household. As a result, while a state may have sufficient information during the *ex parte* process to renew Medicaid or CHIP coverage for some individuals in a multi-member household, states are sending renewal forms requesting information for all household members, and, if the renewal form is not returned, states are disenrolling all individuals in the household, including those who should have been determined to be eligible through the *ex parte* process. As discussed in more detail below, these actions violate federal renewal requirements and must be addressed immediately.

To date, CMS has identified that this issue most commonly affects:

- Children in households with at least one adult enrolled in Medicaid. Medicaid and CHIP eligibility levels for children are generally higher than those for adults, and many children are frequently able to be determined eligible through the *ex parte* process, even if additional information may be needed to determine ongoing eligibility for parents or other adults in the household. While the Medicaid income eligibility limit for adults enrolled based on modified adjusted gross income (MAGI) in most states is at or below

State Update

Impeachment Trial Update

- In May 2023, the Texas House voted to adopt 20 articles of impeachment against the AG.
- The Senate began its impeachment trial for suspended Attorney General Ken Paxton on September 5th.
- The chamber has been rearranged in a courtroom-style; a witness stand has been built and added.
- Lt. Governor Dan Patrick is presiding and an appointed outside trial judge is assisting; there are also legendary attorneys that have been hired by the House and by AG Paxton.
- The trial proceedings are public and are livestreamed, with tickets required for entrance into the Senate gallery.

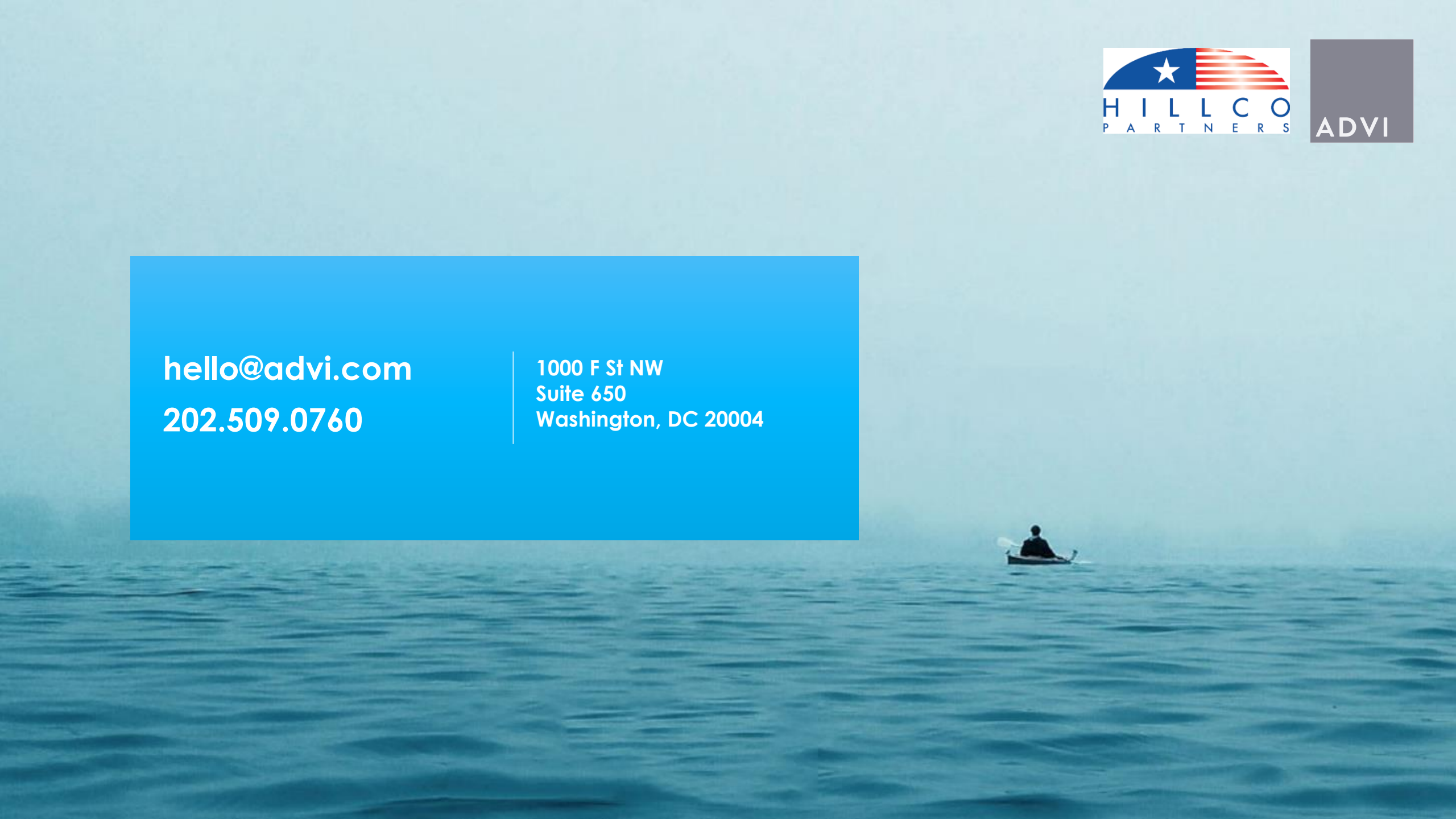
Special Session on the Horizon

- Upon conclusion of the impeachment trial, it is widely expected that Governor Abbott will call the Legislature into a special session to address school choice/vouchers.
- The House has resisted efforts to pass legislation and does not seem poised to make a deal at this point.
- Although members can propose legislation on any topic during a special session, the only items that can make it to the Governor's desk are those that are specifically on the call.
- In addition to school choice, there are numerous rumors that there is increasing pressure for the Governor to extend vaccine mandate bans to private businesses.

Retirements

News of retirements have slowly come out since the end of the 2nd special session in July; these include:

- Rep. Abel Herrero (D), Corpus Christi
- Rep. Julie Johnson (D), Dallas – she is running for U.S. Congress
- Rep. Tracy King (D), Uvalde
- Rep. Lina Ortega (D), El Paso
- Rep. Four Price (R), Amarillo
- Rep. John Raney (R), College Station
- Rep. Matt Schaefer (R), Tyler – current chair of the House Freedom Caucus
- Rep. Carl Sherman (D), Dallas – running for an opportunity to run against Sen. Cruz
- Rep. Ed Thompson (R), Pearland
- Sen. Roland Gutierrez (D), San Antonio –running for an opportunity to run against Sen. Ted Cruz



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