TxSCO Update

April 11, 2024

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Overview: Notable Updates

Federal

- Provider Reimbursement
  - Medicare Payment Cuts
  - MACRA Reforms: Senate Working Group
  - NYT: MultiPlan's Impact on Provider Reimbursements
- In-Office Dispensing
- Medicaid Unwinding: Updated Estimates
- Cancer Moonshot: Patient Navigator Services
- 340B: The latest
- PBMs: The latest
- Artificial Intelligence update

State

- Primary Elections Results
- Major Takeaways
- Voter Turnout
- Incumbents Who Lost
- New Members
- Upcoming Runoffs
- Returning Incumbents
- Final Whitebagging rule

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Federal Updates

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Medicare Provider Reimbursement: The Latest

Following the first Minibus containing a "skinny" health package (March 8th), Congress passed a second Minibus (March 22nd), funding HHS through the remainder of FY 2024.

"Skinny" Health Package: March 8, 2024

- 1.68% prospective payment increase to Medicare physician pay combined with a previously established 1.25% payment increase, leading to a –0.44% payment change for 2024 across all specialties, starting March 9, 2024
  - In the CY 2024 PFS final rule, CMS finalized a -3.37% rate change for physician pay
  - Note: Different specialties may see different impacts of the physician pay adjustment
- 1.88% increase to Advanced Alternative Payment Model (APM) bonuses, compared to a 3.5% extension in 2023
- $4.27B in funding for community health centers for FY24
- One year delay in scheduled disproportionate share hospitals (DSH) pay cuts
- Requirement for state Medicaid plans to cover medication-assisted treatment for substance use disorder

Second Minibus: March 22, 2024

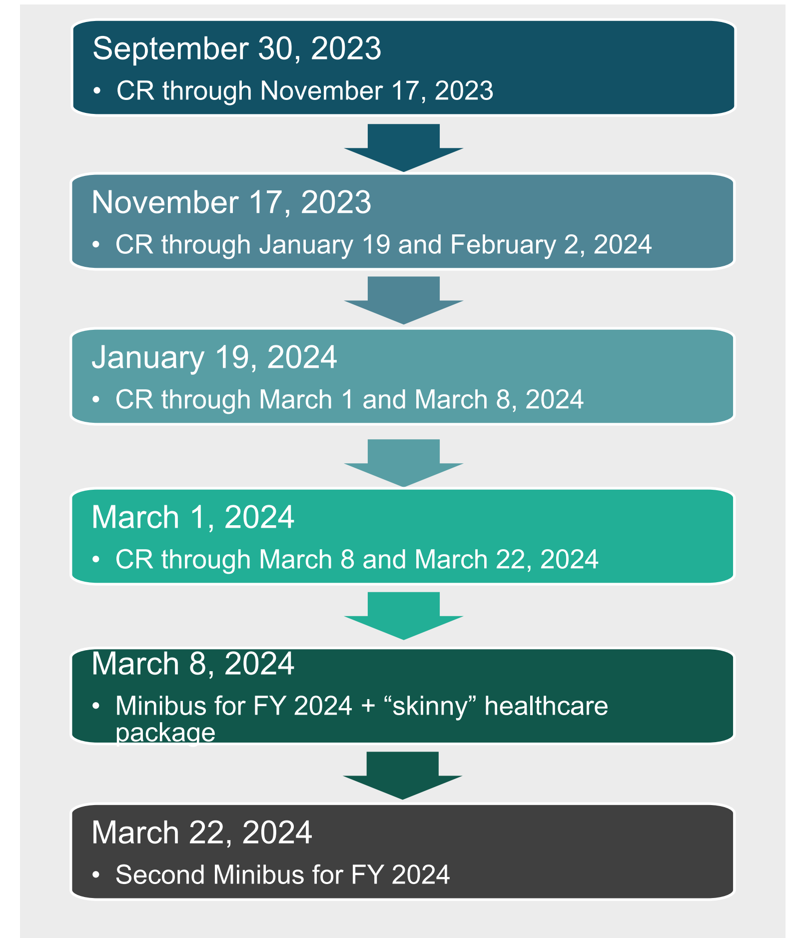
- Increase in funding for cancer research by $120M, Alzheimer's research by $100M, and mental health research by $75M
- Additional $1.9B in funding for community health centers

Exclusions

- While legislation addressing PBMs, site-neutral payments, and other SUPPORT Act reauthorizations were not included in this package, these provisions could be included in later bills.

"***It is a real missed opportunity that these critical, bipartisan provisions will be unnecessarily delayed until December or longer***"

– Statement from Senate Finance Committee Chair Ron Wyden, D-OR



Source: Stat (3/3/24, link); IHP (3/3/24, link); Modern Healthcare (3/4/24, link); Sen. Finance Press Release (3/5/24, link); Modern Healthcare (3/22/24, link)

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MACRA Reforms: Senate Working Group

Members

- Sens. Catherine Cortez Masto (D-NV),
- Marsha Blackburn (R-TN),
- John Barrasso (R-WY),
- Debbie Stabenow (D-MI),
- Mark Warner (D-VA), and
- John Thune (R-SD)

Goals

- Propose changes to the Physician Fee Schedule
- "Make necessary updates" to MACRA
- "Ensure financial stability for providers, improve patient outcomes, promote access to quality care, and incentivize the utilization of emerging health care technology"

"As the health care system has evolved since the inception of the Medicare program, the physician payment system has failed to keep pace with the actual cost of care and the improvements in new services and technologies…Despite efforts like [MACRA], which made significant strides towards a value-based payment system, further action is needed to address reimbursement challenges and shift toward a system that aligns payment incentives with patient outcomes." – Medicare Payment Reform Working Group

Source: Fierce Healthcare (2/9/24, link)

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NYT: Third-Party Company MultiPlan Lowers Provider Reimbursement, Increases Insurer Payments

Overview

- For employer-based insurance, when a patient receives out-of-network care, the patient's payer may send the bill to MultiPlan.
- MultiPlan uses reference-based pricing and its AI tool to recommend an amount to pay the provider.
- The employer and the insurer receive processing fees from the employer; the lower the amount paid to the provider, the higher the processing fee.

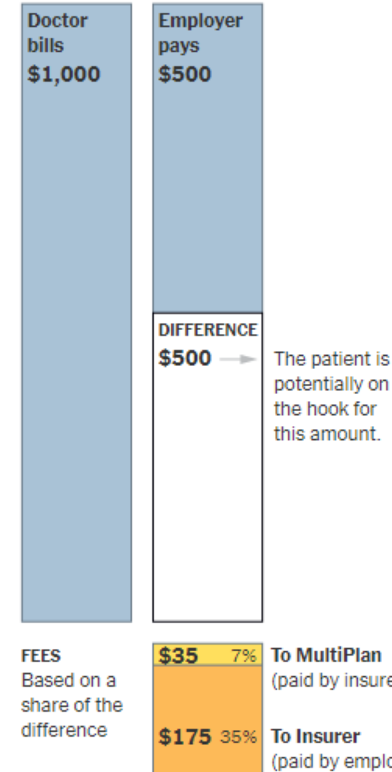
Concerns Raised

- Employers are unable to predict the processing fee costs, and costs continue to rise.
  - One union health plan reported paying $550,000 in fees in 2016 and $2.6M in fees in 2019.
- Patients are faced with balanced bills.
- Providers are being reimbursed at low rates, with a limited ability to negotiate with MultiPlan.

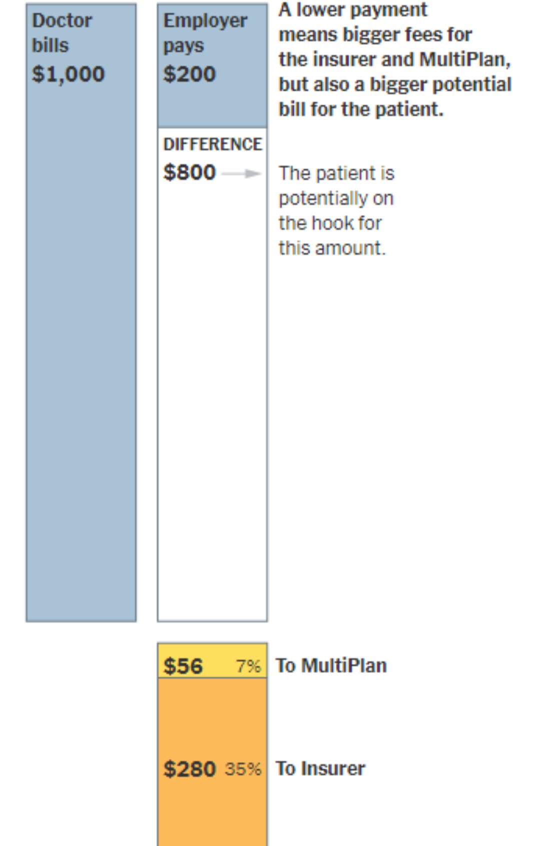
How MultiPlan and Insurers Make Money on Fees

MultiPlan and health insurers typically receive a percentage of the "savings" on each claim, creating an incentive to recommend lower payments.

EXAMPLE 1:
MULTIPLAN ADVISES A 50% PAYMENT



EXAMPLE 2:
MULTIPLAN ADVISES A 20% PAYMENT



Fee percentages vary based on negotiated contracts. · By The New York Times

Source: New York Times (4/7/24, link); MultiPlan (link)

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Update: House E&C Health Subcommittee Advances the Seniors' Access to Critical Medications Act; Full E&C Committee Declines to Mark Up Bill

H.R. 5526, introduced in September 2023, would exempt in-office dispensers and mail shipping from the Stark Law

Sponsor and Co-Sponsors

Rep. Diana Harshbarger
(R-TN-1)

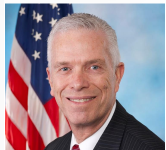
Rep. Debbie Wasserman Schultz
(D-FL-25)*

Rep. Chuck Fleischmann
(R-TN-3)*

Rep. Donald Davis
(D-NC-1)*

Rep. Mariannette Miller-Meeks
(R-IA-1)*

Rep. Troy Balderson
(R-OH-12)*



Rep. Bill Johnson
(R-OH-6)

Rep. Richard Hudson
(R-NC-9)

Rep. Lisa Blunt Rochester
(D-DE-At Large)

*** Denotes original co-sponsor**

Overview

- H.R 5526, the Seniors' Access to Critical Medications Act, would do the following:
  - Amends Section 1877 of the Social Security Act to clarify that mailing medications and allowing family members/caregivers to pick up medications on behalf of a patient will not violate the Stark Law
  - Rescinds CMS FAQs related to the topic
- 57 cosponsors as of Nov. 13

Timeline

- 9/18/23: Introduced in House; referred to Energy & Commerce and Ways & Means Committees
- 10/19/23: Bipartisan support voiced at House Energy and Commerce Hearing
- 3/12/24: Passed by the House Energy & Commerce Health Subcommittee, 19-6
- 3/20/24: House Energy & Commerce Committee excluded H.R. 5526 from its markup session, with Rep. Pallone (D-NJ-6) stating that exempting mail shipping could encourage the over-prescribing of drugs

Source: H.R.5526 (link); IHP (3/19/24, link)

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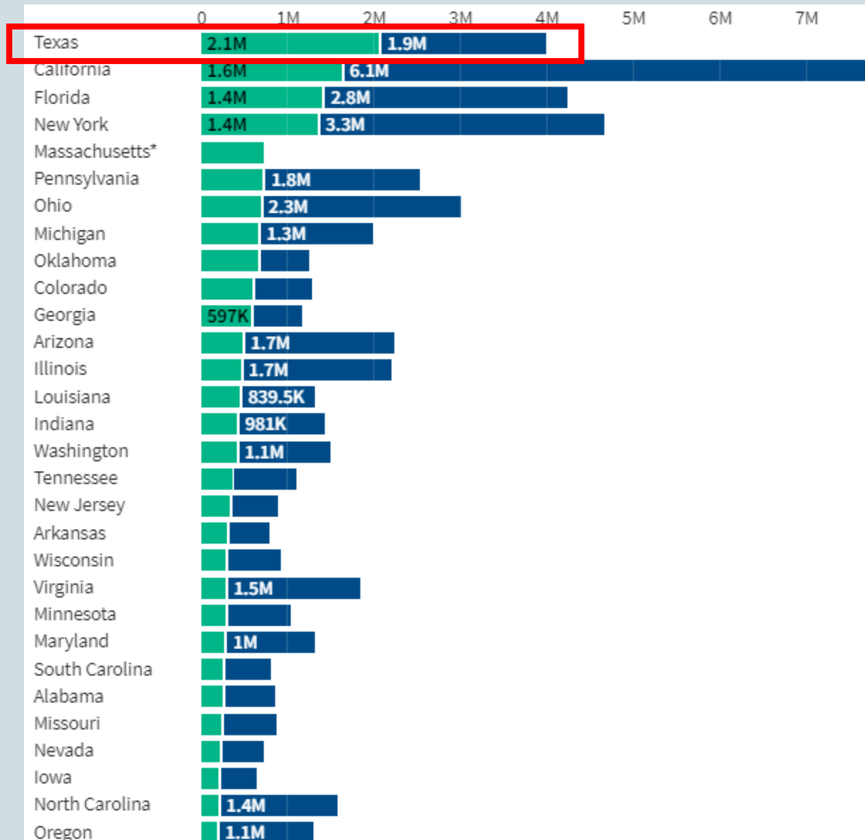
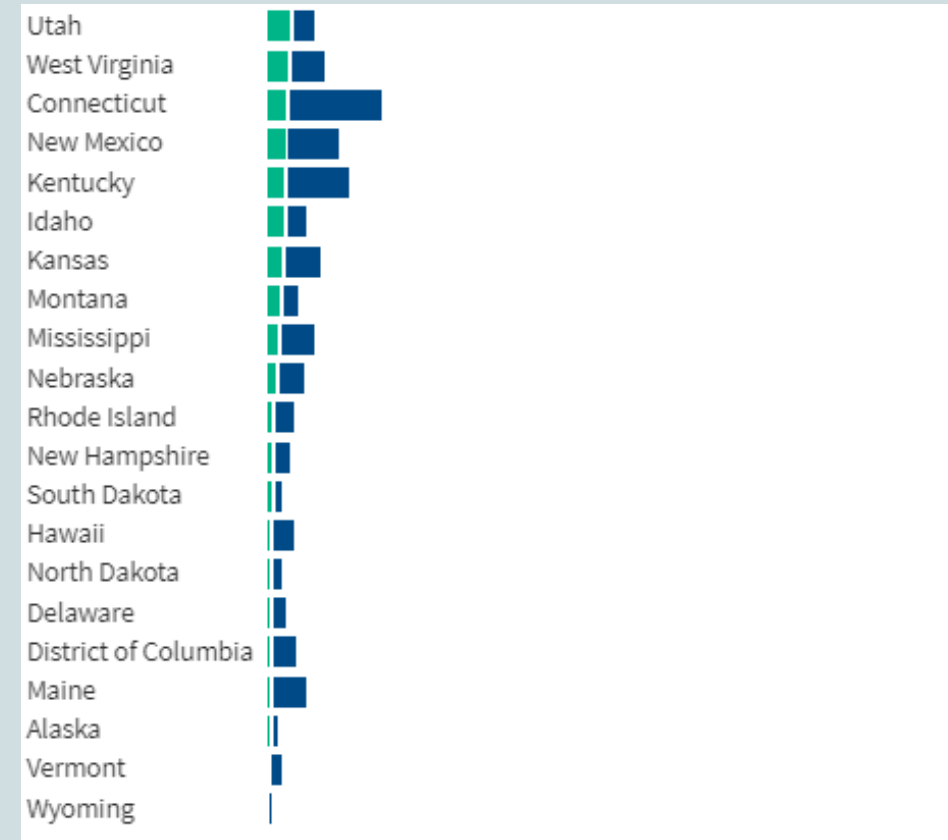
Medicaid Unwinding: Updated Estimates

KFF

As of April 4, 2024, KFF figures show at least 19.6M Medicaid enrollees have been disenrolled and 42.3M have had their coverage renewed.





Disenrolled Coverage Renewed

Source: KFF (4/4/2024, link)

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Public-Private Partnerships Announced in Cancer Moonshot

March 8, 2024: White House announced commitments from health insurers and oncology providers to increase access to **patient navigation services**.

Background

- In the CY 2024 Physician Fee Schedule final rule, CMS finalized the addition of new patient navigation codes, which will reimburse care navigation as part of a treatment plan for certain diseases.
- Covered services include a person-centered assessment, referrals to supportive services, health system navigation, and facilitating behavioral change.

Overview

- Insurers and providers have committed to the following:
  - Providing and covering navigation services,
  - Capturing utilization of navigation codes across patient demographics,
  - Tracking associated health outcomes of patients benefitting from navigation services, and
  - Supporting the provision of navigation services in accordance with the Oncology Navigation Standards of Professional Practice.
- **Plan and provider associations have committed to providing member education on the use of these codes.**

"Together, through the Biden Cancer Moonshot, we're building a world where our power is greater than ever before, where patients and their families have a trusted navigator by their side, where no person has to face cancer alone." – Dr. Jill Biden

Participating Comprehensive Cancer Centers and Community Oncology Practices

- Abramson Cancer Center
- AIS Cancer Center | Adventist Health Bakersfield
- Atrium Health Wake Forest Baptist Comprehensive Cancer Center
- Baptist Health Cancer Care
- City of Hope
- Dana-Farber Cancer Institute
- Duke Cancer Institute
- Herbert Irving Comprehensive Cancer Center
- Huntsman Cancer Institute at the University of Utah
- Marian Regional Medical Center | Mission Hope Cancer Center
- Masonic Cancer Center, University of Minnesota
- Mayo Clinic Comprehensive Cancer Center, Jacksonville, FL
- Mayo Clinic Comprehensive Cancer Center, Phoenix and Scottsdale, AZ
- Mayo Clinic Comprehensive Cancer Center, Rochester, MN and the Upper Midwest
- Mercy Health
- Mercy Health System's Oncology Practices
- Mercy Health/Lourdes Hospital Cancer Center
- Moores Cancer Center at UC San Diego
- Northwell Health
- Nuvance Health
- Ochsner LSU Health Shreveport
- Ohio State University Comprehensive Cancer Center
- Penn State Cancer Institute
- Sidney Kimmel Cancer Center
- St. Elizabeth Healthcare
- St. Luke's Cancer Institute
- Sutter Health Memorial Medical Center
- The Cancer Center at Mercy Hospital Joplin
- The Fred and Pamela Buffett Cancer Center
- UChicago Medicine Comprehensive Cancer Center
- University Hospitals Seidman Cancer Center
- University of Colorado Cancer Center
- University of Maryland Marlene and Stewart Greenebaum Comprehensive Cancer Center
- University of New Mexico Comprehensive Cancer Center
- UPMC Hillman Cancer Center
- USC Norris Comprehensive Cancer Center
- UVA Comprehensive Cancer Center
- Vail Health Shaw Cancer Center
- Wilmot Cancer Institute at University of Rochester
- Winthrop P. Rockefeller Cancer Institute

Participating Health Insurers

- Aetna
- Blue Cross Blue Shield of Minnesota
- Elevance Health
- Health Alliance Plan
- Humana
- Priority Health
- Select Health

Participating Plan and Provider Associations

- Alliance of Community Health Plans (ACHP)
- Association of American Cancer Institutes (AACI)
- Association of Cancer Care Centers (ACCC)
- AHIP
- Blue Cross Blue Shield Association (BCBSA)
- Community Oncology Alliance (COA)
- Self-Insurance Institute of America (SIIA)

Source: White House Press Release (3/8/24, link); Remarks prepared for Jill Biden (3/27/24, link)

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340B Updates

Federal

- SUSTAIN 340B Act discussion draft legislation released in February:
  - Bipartisan bill drafted by Sens. Thune (R-SD), Stabenow (D-MI), Capito (R-WV), Baldwin (D-WI), Moran (R-KS), and Cardin (D-MD).
  - Prohibits manufacturer contract pharmacy policies.
  - Increases covered entity requirements.
  - Institutes a covered entity user fee.
- 340B Patients Act released in March by Rep. Matsui (D-CA-7):
  - Requires manufacturers to extend 340B pricing to covered entities' contract pharmacies.

State

- At least 21 states have introduced or passed some form of 340B contract pharmacy legislation, largely prohibiting manufacturers from instituting restrictions on contract pharmacies.
- Texas legislators may look to introduce similar legislation during their next legislative session.

Source: SUSTAIN 340B Act Full Text (2/2/24, link); Rep. Matsui Press Release (3/12/24, link)

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PBM Updates

Congress

- PBM reform was excluded from both spending packages passed in March.
- After PBM reform was excluded from the March 8 spending package, Sens. Wyden (D-OR) and Crapo (R-ID) sent a letter to the Senate Finance Committee to reaffirm their commitment to enacting meaningful PBM reforms in upcoming spending legislation.

White House

- On March 4, the White House held a roundtable on PBM reform, inviting the FTC, community pharmacists, Gov. Beshear (D-KY), Cost Plus Drugs, and California Blue Shield to speak.
  - Panelists highlighted the need for increased transparency.

Key PBM Reform Legislation

Bill	Description	Likelihood
H.R. 6283, Delinking Revenue from Unfair Gouging (DRUG) Act	• Applies to federal employee plans • Prohibits spread pricing, PBMs deriving revenue other than service fees, and reimbursing a network pharmacy less than the amount a PBM would reimburse an affiliated pharmacy	Low
H.R. 2880, Protecting Patients Against PBM Abuses	• Applies to Part D • Restricts PBM revenue to flat service fees, prohibits charging sponsors costs that differ from what is reimbursed to pharmacies • Requires PBMs to report rebate dollar and percentage amounts, as well as the difference in costs between formulary drugs and therapeutic alternatives	Moderate
H.R. 5378, Lower Costs, More Transparency Act	• Applies to group commercial plans and Medicaid • Requires PBMs to provide employers with data on prescription drug spending and prohibits spread pricing (Medicaid only)	Moderate

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Senate Finance Holds Hearing on AI and Healthcare

Feb. 8, 2024: Senate Finance Committee held a hearing on AI and healthcare. Senators questioned witnesses on their experience working on and researching AI in the healthcare space.

Peter Shen
Siemens Healthineers

- "With the rapid acceleration in development and innovation of AI, the need for the regulatory environment to be able to balance safety, effectiveness, as well as update and improve functionality, without hampering innovation and adoption is critical."
- "While we believe the current regulatory framework is sufficient to support AI innovation, we support the continuation of flexibility in the approval process, as a one-size-fits-all approach could seriously inhibit the potential of AI, as well as efforts to facilitate global harmonization and the development of appropriate international consensus standards."

Mark Sendak
Health AI Partnership

- "We must also address the more critical need for roads, onramps, and bridges—the core infrastructure investments needed to ensure that all people in the US benefit from AI in healthcare."
- Core infrastructure investments are needed for:
  - Technical assistance
  - Technology infrastructure
  - Training

Michelle Mello
Stanford University

- Congress should:
  1. Require healthcare organizations have robust processes for determining whether planned uses of AI tools meet certain standards.
  2. Fund a network of AI assurance labs to develop consensus-based standards and ensure that lower-resourced healthcare organizations have access to necessary expertise and infrastructure to evaluate AI.
  3. Require developers disclose information that consensus-based organizations determine essential to evaluating safety and ethics.
  4. Work with CMS to provide guidance to MA plans about algorithms in coverage decisions.
  5. Ensure relevant federal agencies have clear grants of authority to adopt standards for all types of healthcare AI. Congress must speak clearly when it intends to give authority to agencies.

Ziad Obermeyer
UC Berkeley

- "AI developers must be transparent about the output of their algorithms…outputs should be evaluated for accuracy in a completely independent dataset."
- "AI products should be valued and reimbursed according to established principles from health economics and outcomes research."
- "The sooner public programs lay out what they are looking for, the sooner the market can deliver safe and effective AI products to solve the urgent problems they face."

Katherine Baicker
University of Chicago

- "Predictive AI thus offers much promise at the individual and system level to drive medical innovation, increase the quality of care, and improve patient outcomes – and do so in a way that maintains access and affordability through a focus on high-value use."
- "But that potential hinges on investment in shared data infrastructure and, crucially, on the development of systems of patient protections and algorithm testing and validation that engender trust and ensure broad and equitable patient benefits."

Source: Senate Finance (2/8/24, link, link, link, link, link)

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CTA Gathers Stakeholders to Guide AI Healthcare Reform

On March 13, the Consumer Technology Association (CTA) released a memo entitled "What is Health AI?" CTA noted this is a first step in creating a "common understanding" for regulators of the uses of Artificial Intelligence (AI) in the healthcare system.

Overview

- The CTA convened a group of health associations coalitions, and other stakeholders to develop resources for policymakers to with the goal of advancing safe and effective healthcare-related AI policies.
  - **Developed materials are targeted for the Congressional Digital Health Caucus, which is currently trying to determine Congress' role in implementing Health AI regulations and standards.**
- Stakeholders in the coalition include: AdvaMed, AHIP, American College of Cardiology, Alliance of Community Health Plans, Blue Cross Blue Shield Association, Coalition for Health AI, Council of Medical Specialty Societies, Digital Medicine Society (DiMe), and Laura Adams, Senior Advisor, National Academy of Medicine.
- Stakeholders interested in getting involved with the CTA can apply to join their Health Division Member Group here.

"What is Health AI?" Summary

- The brief outlines a general summary of Health AI, focusing on its predictive and generative capabilities, and noting the rapid advancement in the field.
- CTA claims that AI can generally be used to improve decision-making, enhance communication and patient access, streamline processes, and integrate datasets.
  - CTA specifically highlights AI applications in healthcare, including:
    - **Administrative Processes** – Scheduling, patient intake, claims processing, referral tracking
    - **Operational support** – quality measure data collection/analysis
    - Clinical decision support: software to help providers analyze patient data and interpret clinical guidelines.
    - **Population Health Interventions**
    - **Medical Devices** – using AI to aid in treatment or diagnosis
    - **Drug Discovery** – identifying new molecules for drug development or new treatments based on existing drugs

CTA states that it will engage in future collaborations with the healthcare industry to develop other educational resources (no additional information provided as of March 14, 2024). Three additional white papers will be released in 2024 on health AI topics, including ones focused on data privacy, bias, and reimbursement.

Source: CTA Press Release (3/13/24, link); CTA Brief "What is Health AI?" (3/13/24, link)

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State Updates

Major Takeaways

- Endorsements from Governor Abbott and Trump were significant.
- Voting for the impeachment of AG Paxton negatively impacted incumbents.
- Money matters
  - According to 30-day-out and 8-day-out reports. Gov Abbott has spent more than ever on State House candidates and challengers.
    - **Challengers:** Governor Abbott spent a total of $4,628,186 on challenger candidates, with an average spend of $462,818.60 per candidate.
    - **Incumbents:** For incumbent candidates, the total spend was $1,184,342, with an average spend of $78,956.13 per candidate.
    - **Open Seats:** The spend on open seat races amounted to $679,002, with an average spend of $97,000.29 per candidate.

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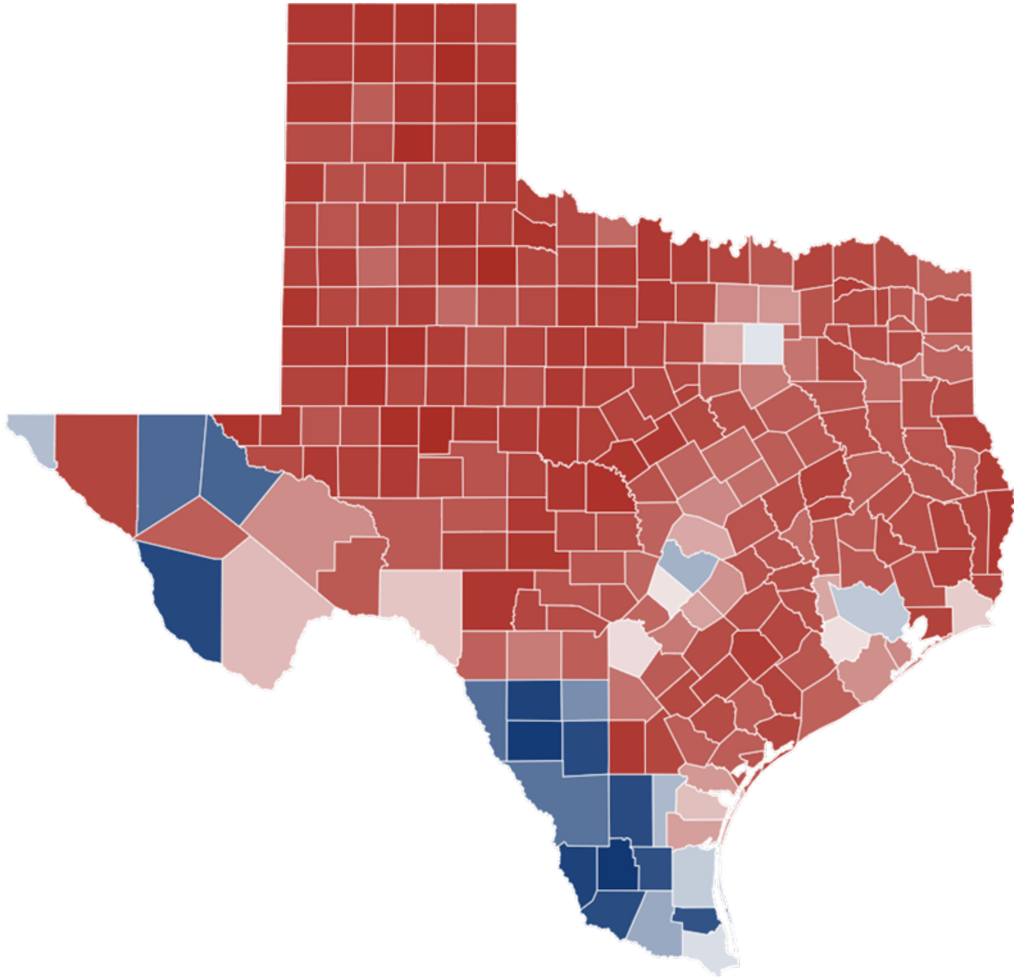
Voter Turnout Comparison



2024 Stats (Presidential)

2024 Total Registered: 17,948,242 (March 2024)

2024 R March Primary Voters: 2,258,483 (12.58% of registered voters during primary)

2024 D March Primary Voters: 1,028,256 (5.73% of registered voters during primary)

2024 Total Primary Voters: 3,286,739 (18.31% of registered voters during primary)

2022 Stats (Gubernatorial)

2022 Total Registered: 17,672,143 (November 2022)

2022 November General Turnout: 8,102,908 (45.85% of registered voters during general election)

2022 R March Primary Voters: 1,954,172 (11.05% of registered voters during primary)

2022 D March Primary Voters: 1,075,601 (6.09% of registered voters during primary)

2022 Total Primary Voters: 3,029,773 (17.14% of registered voters during primary)

2020 Stats (Presidential)

2020 Total Registered: 16,955,519 (November 2020)

2020 November General Turnout: 11,315,056 (66.73% of registered voters during general election)

2020 R March Primary Voters: 2,017,167 (12.44% of registered voters during primary)

2020 D March Primary Voters: 2,094,428 (12.92% of registered voters during primary)

2020 Total Primary Voters: 4,111,595 (25.36% of registered voters during primary)

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Incumbents Who Lost

- Steve Allison – Allison began serving San Antonio in 2019 and serves on Appropriations and the Select Committee on Youth Health & Safety. He voted to impeach Ken Paxton and did not support school vouchers. Marc LaHood prevailed in this race.
- Ernest Bailes – served southeast Texas (Liberty, Hardin, and San Jacinto counties) since 2017; regarded as one of the largest champions of public education; Trump, Abbott and Paxton all endorsed his challenger Janis Holt.
- Travis Clardy – served Nacogdoches since 2013; lost to Joanne Shofner – Clardy did not support school vouchers, which led to Governor Abbott endorsing Shofner; Trump also endorsed against Clardy.
- Jill Dutton – Dutton won a seat in a special election, but lost to her previous challenger Brent Money.
- Jacey Jetton – served Fort Bend County since 2021; huge champion for children's hospitals and children's mental & behavioral health care – he also serves on House Appropriations and is the Chair of the Health and Human Services subcommittee and serves on Public Health. He voted to impeach Paxton, which has been identified as one of the biggest reasons for his loss to Matt Morgan.

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Incumbents Who Lost

- Glenn Rogers – a veterinarian who began serving the Mineral Wells area in 2021; Abbott endorsed his opponent, due to Rogers' willingness to support school vouchers; he also voted to impeach Paxton.
- Hugh Shine – is serving the Temple area in his second round in the Legislature, which started in 2017; largely seen as a leader on property tax issues. Abbott endorsed his challenger, Hillary Hickland, due to Shine's unwillingness to support school vouchers; Shine also voted to impeach Paxton.
- Reggie Smith – began serving Sherman in 2019 and served on the House Committee on Public Health. He voted to impeach Paxton. He lost to Shelley Luther, who became a public figure when she fought to keep her hair salon open during the COVID-19 pandemic.
- Kronda Thimesch – Thimesch is a freshman from Denton who voted to impeach Paxton. She lost to Mitch Little, who defended Paxton in the Senate impeachment trial of Paxton.

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New Members – Who Are They?

- Hillary Hickland – Belton
  - Has advocated for children and families at the Capitol
  - Priorities include school vouchers and "limiting what children can access on social media, protecting them from sexual predators and big tech."
- Janis Holt – Silsbee – No General Election
  - Serves as Board President of Silsbee Independent School District and is pro-school vouchers.
- Marc LaHood – San Antonio
  - Criminal defense attorney
  - Priorities include border security, lowering property taxes, and school choice.
- Mitch Little - Dallas
  - Business attorney who defended Paxton during the Senate impeachment trial
  - Priorities focus on election integrity, border security, and maintaining conservative values in schools.
- Shelley Luther – Tom Bean, Grayson County
  - Former school teacher and owner of a hair salon
  - Will fight against government mandates; wants to secure the border, and eliminate property taxes.

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New Members – Who Are They?

- Brent Money - Greenville
  - Real estate attorney who previously served on the Greenville city council and as the city attorney
  - Adopted children through foster care and is a strong advocate for parental rights.
- Matt Morgan - Katy
  - Owns an insurance adjustment business
- Mike Olcott – Aledo, Parker County – No General Election
  - Left medical school to pursue a Ph.D in Biochemistry; spent his career "conducting research that could one day help stop or slow the growth of cancer cells."
  - Two top priorities are "protecting our children" and "medical freedom" through supporting "a bill that unequivocally bans vaccine mandates."
- Joanne Shofner – Nacogdoches – No General Election
  - Trained Christian Life Coach; former manager for Hyatt Hotels.
  - One of her four priority areas is to "protect children," including stopping the sexualizing of children through indoctrination in schools; stopping big tech and predators from preying on children; solidify parental rights and freedom for school choice; and she is 100% pro-life.
  - She also prioritizes protecting medical freedom.

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Incumbents Who are in Runoffs – Tuesday, May 28th

- House Speaker Dade Phelan
- Voted against school vouchers and voted to impeach Ken Paxton:
  - Gary Van Deaver, Justin Holland, John Kuempel, and DeWayne Burns
- Supported school vouchers and voted to impeach Ken Paxton:
  - Frederick Frazier, Lynn Stucky, and Stephanie Klick
- Democrat Shawn Thierry – voted against school vouchers, voted for SB 14 and HB 900

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Runoffs for Open Seats

- The winners of the following races will have a general election opponent:
  - Jarvis Johnson vs. Molly Cook – Senate District 15 (Whitmire)
  - Brent Hagenbuch vs. Jace Yarborough – Senate District 30 (Springer)
  - Trey Wharton vs. Ben Bius – House District 12 (Kacal)
  - Jeffrey Barry vs. Alex Kamkar – House District 29 (Ed Thompson)
  - Jeff Bauknight vs. A.J. Louderback – House District 30 (Morrison)
  - Democrats Cecilia Castellano vs. Rosie Cuellar – House District 80 (Tracy King)
  - Democrats Diane Symons vs. Carlos Walker – House District 97 (Goldman)
  - Republicans Cheryl Bean vs. John McQueeney – House District 97 (Goldman)
- The winners of these races will become members-elect:
  - Vince Perez vs. Norma Chavez – House District 77 (Ortega)
  - Angeanette Thibodeaux vs. Charlene Ward Johnson – House District 139 (Jarvis Johnson)

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Open Seats with a General Election

- Cody Grace (D) vs. Daniel Alders (R) – House District 6 (Schaefer)
- Solomon Ortiz (D) vs. Denise Villalobos (R) – House District 34 (Herrero)
- Joe P. Herrera (D) vs. Wes Virdell (R) – House District 53 (Murr)
- Erin Shank (D) vs. Pat Curry (R) – House District 56 (Anderson)
- Timothy W. Gassaway (D) vs. Caroline Fairly (R) – House District 87 (Price)
- Cassandra Hernandez (D) vs. John Jun (R) – House District 115 (Julie Johnson)

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Incumbents without General Election Opposition

Republican

- Trent Ashby
- Cecil Bell
- Greg Bonnen
- Dustin Burrows
- Drew Darby
- Mano DeAyala
- Cole Hefner
- Ryan Guillen
- Sam Harless
- Brian Harrison
- Ken King
- Stan Kitzman
- Brooks Landgraf
- John Smithee
- Steve Toth

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Incumbents without General Election Opposition

Democrat

- Alma Allen
- Rafael Anchia
- Diego Bernal
- Salman Bhojani
- Terry Canales
- Nicole Collier
- Lulu Flores
- Erin Gamez
- Barbara Gervin-Hawkins
- Mary Gonzalez
- Gina Hinojosa
- Donna Howard
- Venton Jones
- Oscar Longoria
- Ray Lopez
- Christian Manuel
- Joe Moody
- Sergio Munoz
- Claudia Ordaz
- Ana-Maria Ramos
- Richard Pena Raymond
- Ramon Romero
- Toni Rose
- Jon Rosenthal
- Armando Walle
- Gene Wu
- **Linda Garcia (replacing Neave)
- ** Aicha Davis (replacing Sherman

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Final White Bagging Rule

- The Texas Department of Insurance adopted the final rule implementing HB 1647, the whitebagging bill.
- Many organizations provided testimony including TAHP who asked for the term “provider” to be changed to “pharmacy”
- The agency decided to leave the term out altogether which provides for the correct interpretation of the bill.

Final Text –

28 TAC §3.3708. Payment of Certain Out-of-Network Claims.

(f) An insurer must cover a clinician-administered drug under the preferred level of coverage if it meets the criteria under Insurance Code Chapter 1369, Subchapter Q, concerning Clinician-Administered Drugs ~~even if it is dispensed by a nonpreferred provider~~.

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APPENDIX

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Meet Baby Madeline (and Dawson) Greenleaf!

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HHS White Paper on Drug Shortages: Proposed Solutions

On April 2, 2024, HHS released a white paper outlining the current state of drug shortages, current actions being taken by HHS, and proposed policies to eliminate shortages. The proposed policies would require Congressional action.

Manufacturer Resiliency Assessment Program (MRAP)

- Through a public-private partnership, a private entity administering the MRAP would assign resilience scores to manufacturers of generic drugs.
- Scores would be based on an assessment of manufacturer practices and past performance., with metrics reflecting quality management maturity, manufacturing redundancy, and sourcing diversity.
- Manufacturers would be incentivized to participate based on the expectations that hospitals would use this information in their purchasing decisions.
- MRAP implementation would likely begin by focusing on the drugs in ASPR’s list of critical medicines, or a larger set that incorporates chemotherapeutic drugs.

Hospital Resilient Supply Program (HRSP)

- The HRSP would link Medicare payments and/or penalties to hospitals based on a combination of attestation and ratings related to drug shortages.
- Attestations or other resilience-oriented activities that could be considered include:
  - Hospital inventory management practices.
  - Hospital contracting practices with middlemen that promote supply chain resilience.
- The scorecard could also incorporate manufacturer resilience ratings from the MRAP.
- HRSP implementation would be a long-term effort.

Other Proposals

- Require drug manufacturers to notify FDA of an increase in demand that the manufacturer will likely be unable to meet for certain drugs.
- Require labeling to include the original manufacturer of API and finished dosage form for quality purposes.
- Provide authority for acquisition, construction, or alteration of non-federally owned facilities, which would allow ASPR to support efforts to develop domestic manufacturing capacity.
- Increasing payments for generics to stimulate supply.
- Facilitating public-private partnerships and emerging manufacturing and distribution models.
- Exploring federal stockpiling.

While most industry groups have not released a response to the white paper, the American Society of Health System Pharmacists (ASHP) stated, "The HHS proposal misses the mark by suggesting penalties against hospitals that do no adopt HHS-required inventory and purchasing practices...This risks further disadvantaging hospitals with limited resources to manage shortages."

Source: White Paper (4/2/24, link); ASHP (4/3/24, link)

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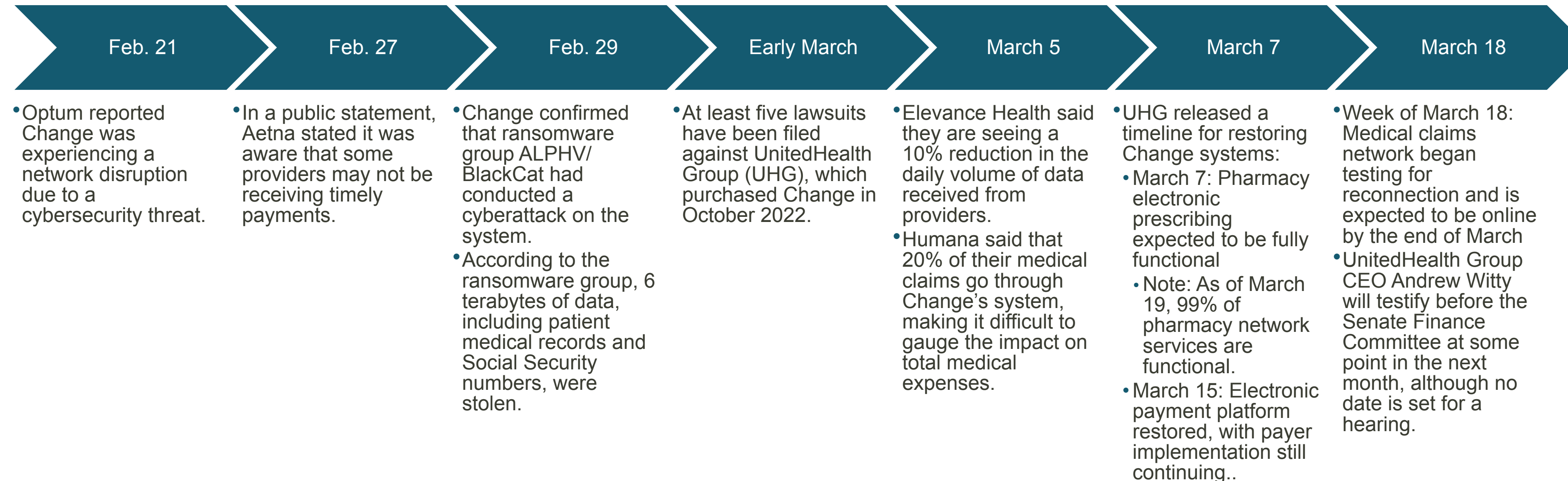
Change Healthcare Cyberattack: Timeline and Implications

Since February 21, Change Healthcare has been shut down due to a cyberattack. This attack has been described by Becker's Healthcare as “the most significant and consequential cyberattack in American history.”

Change Healthcare Overview

- Change Healthcare serves as a middleman among insurers, other clearinghouses, and providers, transferring claims data.
- Data transmitted by Change include medical claims, prior authorization requests, medical attachments (including physician notes), eligibility inquiries and responses, and electronic remittance advice transactions.
- In the U.S., Change handles data from 1 in 4 patient records, 6,000 hospitals and health systems, 1M physicians, and 39,000 pharmacies, totaling 15B healthcare transactions and $1.5T in healthcare claims.



- The cyberattack has had a significant impact on providers and patients, with an AHA survey reporting that 74% of hospitals are facing a direct impact on patient care.
- According to Kodiak Solutions, the total estimated cash flow impact for hospitals through March 9 is $6.3B in delayed payments.
- News stories have reported instances of patients paying out-of-pocket for prescription drugs and of hospital discharges being delayed.

Source: Becker’s Health IT (3/15/24, link); Stat News (3/4/24, link); Court presentation from *United States of America, et al. v. UnitedHealth Group Inc. & Change Healthcare Inc.* (accessed 3/19/24, link)

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Change Healthcare Cyberattack: Responses

UnitedHealth Group

- **Temporary Funding Assistance Program**
  - Providers impacted by the cyberattack can apply for temporary funding based on the difference between historical weekly claims/payments volume pre-disruption compared to weekly volume post-disruption.
  - Once standard payment operations resume, providers will have 45 business days to repay the temporary funds.
- **Prior Authorization Suspensions**
  - UHG is temporarily suspending prior authorizations for the following in Medicare Advantage plans and D-SNPs:
    - Most outpatient services **except** DME, cosmetic procedures, and **step therapy for Part B drugs.**
    - MA inpatient admissions.
    - **Drug formulary exception review processes.**

HHS and CMS

- On March 9, CMS made available Change Healthcare/Optum Payment Disruption (CHOPD) accelerated payments to Part A providers and advance payments to Part B suppliers experiencing claims disruptions.
  - Payments will cover up to 30 days of Medicare claims, and providers/suppliers will have 90 days to repay the accelerated/advance payment.
- On March 13, HHS' Office for Civil Rights (OCR) initiated an investigation into the cyberattack, focusing on whether a breach of PHI occurred and whether Change and UHG have been compliant with HIPAA rules.
- On March 18, an HHS official said that more insurers have agreed to accelerate payments to impacted providers but did not name which insurers had accelerated payments.
- Through June 30, 2024, CMS will not be enforcing certain requirements related to Medicaid State Plan Amendments.
- Clinicians are able to file a MIPS Extreme & Uncontrollable Circumstances Exception application through April 15.
- On March 25, HHS released a summary of provider resources in response to the cyberattack.

Congress

- Sen. Schumer (D-NY): Wrote to CMS on March 4, requesting the agency offer accelerated and advance payments.
- Sen. Crapo (R-ID): Asked HHS to "continue to update members and stakeholders on efforts to limit further disruption."
- Sen. Wyden (D-OR): Called for "fines and accountability for negligent CEOs" in instances like the Change attack.
- Sen. Gillibrand (D-NY): Along with 21 other lawmakers, wrote to HHS and the Department of Homeland Security's Cybersecurity and Infrastructure Security Agency, asking the agencies to address the current cyberattack and prepare for future attacks.
- Sen. Warner (D-VA): On March 22, introduced the Health Care Cybersecurity Improvement Act of 2024, which would require advance payments after a cyberattack to providers that met minimum cybersecurity standards.

Source: UnitedHealth Group (accessed 3/19/24, link); Politico (3/18/24, link); CMS (3/9/24, link; 3/13/24, link; 3/15/24, link); HHS OCR (3/13/24, link); Letter to CMS (3/4/24, link); Modern Healthcare (3/15/24, link); CMS QPP (link); Sen. Warner Press Release (3/22/24, link); Summary of Provider Resources (3/25/24, link)

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