TxSCO Update

June 13, 2024

ADVI & HillCo

Agenda

Federal

- EOM Updates
- 340B
  - E&C Subcommittee Hearing
  - 340B ACCESS Act Introduced
- House Ways and Means Health Subc. Hearing on Independent Practices
- FTC Noncompete Rule Update
- 2024 Election

State

- Runoff Election Results
- Political Winds

Federal Updates

CMMI Announces Updates to EOM and a New Cohort Opportunity

On May 30, 2024, CMMI released a request for applications (RFA) to solicit applications for a second cohort of participants in the Enhancing Oncology Model (EOM) and to highlight changes to the model.

Second Cohort Participants: RFA

- The RFA is for a second cohort of EOM participants and payers.
- The second cohort will begin participation in EOM on July 1, 2025, and end on June 30, 2030, for a 5-year model performance period.
- The first performance period began on July 1, 2023, and the **model test will end on June 30, 2030, for all participants, which is a two-year extension from the original end date of June 30, 2028.**

Application

- Private payers, Medicare Advantage plans, state Medicaid agencies, and Medicaid MCOs are eligible to apply to partner with CMS in EOM.
- Physician group practices and payers that wish to participate in EOM are required to submit an application using the EOM RFA Application Portal.
  - CMS is not soliciting Letters of Intent from potential applicants.
- An internal committee will review completed applications. Prior to application approval, CMS will also conduct a program integrity screening.
- Applications to participate in EOM will be accepted on the basis of completeness, quality of narratives, and the result of a program integrity screening.
- **The application portal for interested applicants will be open from July 1, 2024, to September 16, 2024**.

Sources: CMS EOM RFA (5/30/24, link)

CMMI Announces Updates to EOM and a New Cohort Opportunity

Eligible Participants

- Eligible participants are Medicare-enrolled oncology physician group practices identifiable by a unique federal taxpayer identification number.
- Practices that participate in EOM are required to implement eight Participant Redesign Activities to improve quality of care and will have the option to bill a Monthly Enhanced Oncology Services (MEOS) payment.
  - **MEOS payments will increase from $70 to $110 per individual per month (and to $140 per month for dually eligible individuals).**
- EOM participants are financially responsible for the total cost of care for each attributed episode, which is the six-month period following an eligible Medicare individual's receipt of a qualifying cancer therapy.
- Participants may earn a performance-based payment by meeting a risk-adjusted spending target for their attributed episodes; conversely, they will owe a performance-based recoupment to CMS if total spending in these episodes exceeds a specified percentage of their benchmark amount.
- **For all participants, this threshold for recoupment will increase from 98% of the benchmark amount to 100% of the benchmark amount, beginning for episodes initiating on or after January 1, 2025.**

ADVI Insights: CMMI's decision to open a second cohort for EOM is an acknowledgement of the relatively small number of practices from the first cohort, and the likely forthcoming decreased number of participants in early 2025 after the performance period 1 reconciliation results are available. Further, the increased MEOS payment reflects provider feedback that the incentive to join EOM was insufficient relative to OCM.

Sources: CMS EOM RFA (5/30/24, link)

E&C Subcommittee Hearing on Oversight of the 340B Program

HOUSE COMMITTEE ON ENERGY & COMMERCE

On June 4, 2024, the House E&C Oversight and Investigations Subcommittee held a hearing to discuss the benefits and abuses of the 340B program, reinvestment of program savings into patient care, operations transparency, and policy recommendations for disproportionate share hospital percentages.

Representatives' Opening Statements

- The 340B program spending is only a **fraction of the expenses** for pharmaceutical manufacturers and companies -Castor (D-FL-14)
- The savings from the 340B program ensure **essential services for vulnerable communities**, but larger and more profitable hospital systems are **abusing the program for financial gain**, taking the resources away from patients in need -Rogers (R-WA-5)
- Witnesses at this hearing **lack diversity**. For example, Republicans did not invite a drug manufacturer, and a representative from HRSA was not present -Pallone (D-NJ-6)

Witness' Opening Statements

- **Dr. Anthony DiGiorgio:** Policy reforms should **increase the DSH percent** for eligibility and include outpatient visits
- **Sue Veer:** At Carolina Health Centers, the 340B program enables low-income and un/underinsured individuals to receive their prescriptions while **reinvesting savings** into the health system's early childhood services
- **Dr. William Smith:** Some patients are **charged the full price** of the drug, and some underinsured patients **may pay more** out-of-pocket than the hospital paid for the drug
- **Matthew Perry:** Genesis Healthcare System generates 340B savings on the outpatient side and **reinvests** the savings into the inpatient side in their cancer and trauma center

Successes of the 340B Program

- Carolina Health Centers **integrated pharmacy consultations** into the health system, providing comprehensive care to the whole patient
- Genesis Healthcare System improved the quality of care by **increasing provider training** and investments in **technology** to expand **behavioral health** services and develop the first **trauma center** in the area

Pharmacy Benefit Managers

- **Smith:** Although 99% of contract pharmacies are brick-and-mortar pharmacies, some hospitals **contract with pharmacies thousands of miles away** rather than in-house pharmacies

Recommendations to Prevent 340B Abuse

- **Dr. DiGiorgio:** Congress should implement basic **transparency regulations** on reporting where drugs are being purchased, who the drugs are being purchased for, and what the revenue is for such drugs
- **Veer:** The best transparency metric must include outlining the **overall profile of the populations served** (insurance status, where on the Federal Poverty Level (FPL) certain services operate, among other factors)

Reinvestment of 340B Savings into Patient Care

- **Dr. DiGiorgio:** Patients from wealthier hospital systems will be **sent to safety net hospitals** as the savings of the 340B program on larger hospital systems are not being reinvested into patient care

Source: ADVI Memo (link); E&C Oversight Subcommittee Hearing (link)

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House Republicans Introduce 340B Overhaul Bill

Covered Entities (CEs)

- **Establish new eligibility requirements based on hospital type** (maintains current requirements for critical access and sole community hospitals)
  - Rural hospitals must have at least 60% of annual inpatient discharges who reside in a non-Metropolitan Statistical Area.
- **Require CEs to institute a sliding fee scale for uninsured and privately insured low-income (under 200% FPL) patients.**
  - Prohibit CEs from engaging in aggressive medical debt collection practices
- **Federal grantees must provide access consistent with their grant's scope** and ensure patients are not denied access to 340B medicines based on their ability to pay.

Child Sites and Contract Pharmacies (CPs)

- Establishes additional eligibility criteria for child sites and subgrantees.*
- CP arrangements would be recognized in the 340B statute.
  - Grantees and small rural hospitals would be allowed an unlimited number of CPs, but other **hospitals would be allowed 5 non-mail order CPs**.
  - CPs must provide the same affordability assistance as the CE and take certain steps to prevent diversion and duplicate discounts.
  - CPs must be located in the service area of the CE.

PBMs**

- **Prohibits PBMs from:**
  - Imposing discriminatory contracts on CEs, including:
    - Reimbursing a CE or CP less than what it would reimburse to a non-covered entity or CP.
    - Imposing terms on a CE or CP that differs from a non-covered entity or CP contract in fees, patient restrictions, frequency or scope of audits.
  - Interfering with a patient's choice to receive a 340B drug from a CE or CP.
- **Limit CP and other for-profit third parties to charging flat fair-market value fees** for their services.

On May 28, 2024, Reps. Bucshon (R-IN-8), Carter (R-GA-1), and Harshbarger (R-TN-1) introduced the 340B Affording Care for Communities and Ensuring a Strong Safety-Net Act, or 340B ACCESS Act. (H.R. 8574). **The bill aligns with many of the policy priorities put forth by the Alliance to Save America's 340B Program (ASAP 340B). The groups membership includes community health centers, patient advocacy groups, and PhRMA.**

*Child sites: provide as much Medicaid and charity care as parent hospital or state average (higher of), be in a medically underserved area, have a sliding fee scale, and provide "meaningful" services beyond providing prescriptions. Subgrantee must be a public or non-profit entity.
**Provisions modeled after previously introduced legislation (H.R.2534 and H.R.3290)
Sources: PhRMA Press Release (5/28/24, link); ASAP 340B Press Release (5/28/24, link) and Summary (5/28/24, link); Rep. Bucshon Press Release (5/28/24, link)

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House Republicans Introduce 340B Overhaul Bill

Definitions

- Defines a 340B patient as:
  - Must be seen by a provider employed by a CE at least once a year in person (for most hospitals) or twice a year (for grantees and rural hospitals).
  - CE must maintain a consistent responsibility of care that reflects a direct connection between the patient's medical condition and the services provided.
- Defines the 340B program as:
  - Providing "manufacturer price reductions that enable covered entities, whose mission is to serve underserved or otherwise vulnerable communities, to increase access to affordable drugs and health services for these communities."

Transparency and Oversight

- Establishes a 340B data clearinghouse.
  - Would receive Medicare, Medicaid, and commercial claims data to verify 340B claim eligibility.
- **Require DSH hospitals to report certain information, including**:**
  - **How 340B margin is used.****
  - Medicaid and CHIP outpatient revenue
  - Uncompensated outpatient care
- **Supersedes state legislation by stating that the 340B program is governed exclusively by federal law.**

Targeted Rulemaking Authority

- Grants rulemaking authority to HHS for:
  - **Prevention of Medicaid duplicate discounts and oversight of CEs** (1 year after enactment)
    - Methodologies state Medicaid programs and CE's should use to identify duplicate discounts
    - Procedures state Medicaid programs should use to exclude requests for Medicaid rebates.
    - Requirements for states to provide affected manufacturers a "prompt remedy" to incorrectly billed rebates
  - **Ensuring patient affordability of 340B drugs** (90 days after enactment)
  - **The 340B data clearinghouse** (45 days after enactment)
  - **The CE transparency requirements** (180 days after enactment)

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House Ways & Means Health Subc. Hearing on Independent Practices

May 23, 2024: The Ways & Means Health Subcommittee held a hearing titled "The Collapse of Private Practice: Examining the Challenges Facing Independent Medicine."

Overview

- **The Health Subcommittee heard from a panel of five witnesses on the current status of independent practice.**
  - Witnesses included Jennifer Gholson, MD, a family practitioner from Mississippi; Timothy Richardson, an independent physician from Kansas; Chris Kean, COO of The San Antonio Orthopaedic Group; Seemal Desai, MD, founder of Innovative Dermatology, and Ashish Jha, MD, Dean of Brown School of Public Health.
- **The key concerns of the witnesses were:**
  - Consolidation, including hospital and private equity acquisitions
  - Physician compensation, including providers facing decreasing revenue and the PFS failing to account for inflation
  - Prior authorization (private insurers and Medicare Advantage)
  - The usage of Merit-based Incentive Payment System (MIPS)
  - Facility fees
- **Witnesses also highlighted the impacts on**: rising health care costs, challenges in patient access to care, provider payments, and the overall sustainability of independent practices.

Key Asks from Witnesses

- Annual inflation adjustment increases and long-term reform of Medicare payment systems (MPFS) through adopting: **Strengthening Medicare for Patients and Providers Act (H.R. 2474) and Provider Reimbursement Stability Act of 2023 (H.R. 6371)**
- Site-neutral payments and the continued support of **Lower Costs, More Transparency Act (H.R. 5378)**
- Accelerating the transition to Value Based Care using APMs while reforming quality reporting and performance programs
- Strengthening antitrust enforcement policies
- Budget neutrality
- Increased provider reimbursement with a focus on primary care

Notable Commentary from the Health Subcommittee

- Rep. Sewell (D-AL-7) expressed support for H.R. 2474
- Rep. Chu (D-CA-28) called for increased oversight of AI tools in prior authorization, especially relating to MA
- Rep. Hern (R-OK-1) noted his sponsorship of the FAIR Act (H.R. 3417), which would require separate NPIs for HOPDs
- Rep. Fitzpatrick (R-PA-1) expressed concern over Medicare physician pay decreasing 29% since 2001
- Chairman Buchanan (R-FL-16) and Ranking Member Doggett (D-TX-37) expressed concern regarding the impact of private equity on healthcare

Source: Hearing (5/23/24, (link); Prepared Testimonies (link)

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Update: FTC Releases Noncompete Final Rule

On April 23, 2024, the Federal Trade Commission voted to finalize a new rule to prohibit employers from enforcing noncompetes against workers.

Summary

- The rule states that noncompetes are an unfair method of competition. As a result, the rule prohibits employers from entering into new noncompetes with workers.
- The rule prohibits employers from enforcing noncompetes with workers other than senior executives.
  - Less than 1% of workers are estimated to be senior executives under the final rule.
  - Specifically, the final rule defines the term "senior executive" as **workers earning more than $151,164** who are in a "policy-making position."
- The rule requires employers to notify workers whose noncompetes are no longer enforceable that their noncompetes are no longer in effect and will not be enforced. The FTC provides model language that employers can use to notify employees.
- The rule includes an exception that allows noncompetes between the seller and buyer of a business.

Impact of Noncompetes on Oncology Care

- "Due to mistreatment and to escape workplace toxicity, one of my colleagues left our practice in compliance to our non-compete conditions, even though they caused great hardship. I, too, wanted to leave, but could not because doing so would have harmed my family's well being. What I witnessed in the aftermath was unconscionable. There was a void in patient care and months later, there still is a void. Not only was this physician required to move quite a distance from the practice, he was forbidden to even inform his patients that he was leaving. The practice in turn, did not inform the patients, and when asked, just informed them that he was no longer with the practice. **Consequently, wait times to treat cancers doubled and now have tripled**" (pg. 205, final rule).

Notable Stakeholder Reactions

- "The ban makes it more difficult to recruit and retain caregivers to care for patients, while at the same time creating an anticompetitive, unlevel playing field between taxpaying and tax-exempt hospitals." – **Federation of American Hospitals**
- "We applaud FTC's final rule banning physician noncompete clauses which often harm patients and break continuity of care. This rule will bolster competition and create healthy work environments for physicians while improving access for patients." – **American Academy of Family Physicians**
- Health systems "have a voracious appetite for acquiring independent medical practices or putting those practices out of business by luring their physicians away with above-market employment contracts. As such, if the FTC eliminates existing and future non-compete clauses for physician partners/owners in independent medical practices it will decrease competition, not increase it as may be the case in other industries." – **COA, Proposed Rule comments**
- Four business groups filed a lawsuit in the Eastern District of Texas on April 24, stating that the FTC doesn't have the authority to issue such a broad rule.
- **New: A letter signed by 230 industry associations and chambers of commerce, including the AHA, Federation of American Hospitals, and Advanced Medical Technology Association was sent to the FTC on May 24, calling for a delay in implementing the rule.**

Source: FTC final rule (link); FAH press release (4/23/24, link); AAFP response (4/23/24, link); COA comment letter (3/6/23, link); Stat News (4/24/24, link); U.S. Chamber Coalition Letter (4/24/24, link)

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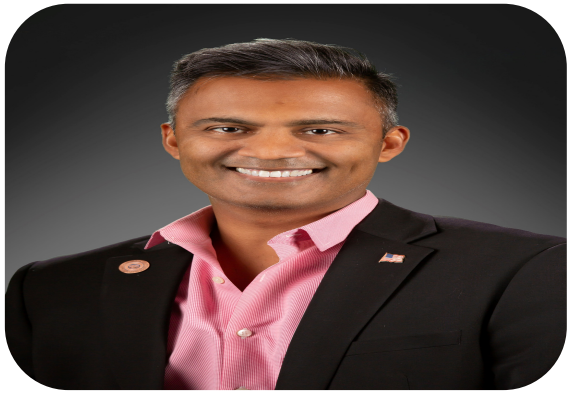
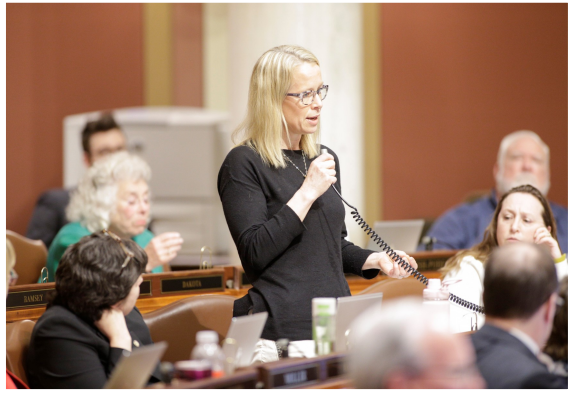
2024 Election: Democratic Doctors Running for Congress



Amish Shaw, MD (AZ)

- Current member of the State House
- Emergency room doctor
- Running against Rep. David Schweikert (R-AZ-1)



Kelly Morrison, MD (MN)

- Current member of the Minnesota Senate
- OB-GYN
- Running unopposed for Rep. Dean Phillip's seat (D-MN-3)

Maxine Dexter, MD (OR)

- Currently serves in Oregon legislature
- Pulmonary and critical care doctor
- Running to replace Rep. Earl Blumenauer (D-OR-3)

Tim Peck, MD (IN)

- Emergency room physician
- Running to flip Rep. Erin Houchin's seat (R-IN-9)

Source: Axios (4/2/24, link)

2024 Election: Latest Polls Show Toss-Ups Across the Board

Today

White House: Biden

Senate: Democrats Control (51D, 49R)

House: Republicans Control (217 R, 213 D, 5 vacant)

2024 Polls

Biden

226 D, 235 R, 77 Toss-up

Toss-up

Trump

Democrat-controlled Senate

48 D, 50 R, 2 Toss-up

Toss-up

Republican-controlled Senate

Must gain 1 seat (Trump wins) or 2 seats (Biden wins) to take control

Democrat-controlled House

Must gain 4 seats to take control

202 D, 210 R, 23 Toss-up

Toss-up

Republican-controlled House

2024 Polls: 270toWin Consensus Forecasts (slide updated May 22, 2024)
White House: 270 electors to win | Senate: 50 or 51 seats to control | House: 218 seats to control

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Trump 2.0: “Foreign Freeloading” Unfinished Business

Donald J. Trump ✓
@realDonaldTrump

Pfizer & others should be ashamed that they have raised drug prices for no reason. They are merely taking advantage of the poor & others unable to defend themselves, while at the same time giving bargain basement prices to other countries in Europe & elsewhere. We will respond!

1:08 PM · Jul 9, 2018

Donald J. Trump ✓
@realDonaldTrump

When you see the Drug Companies taking massive television ads against me, forget what they say (which is false), YOU KNOW THAT DRUG PRICES ARE COMING DOWN, BIG. Favored Nations Clause means USA will pay the lowest price of any nation in the World. Never done before. Watch!!!

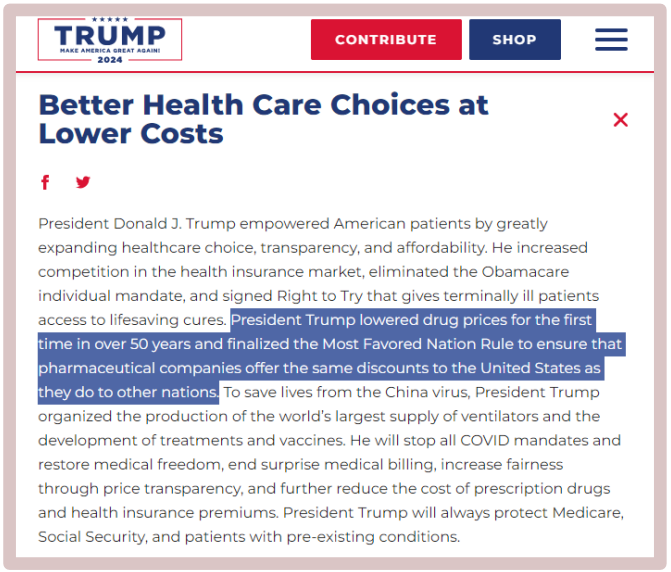
8:01 AM · Aug 2, 2020

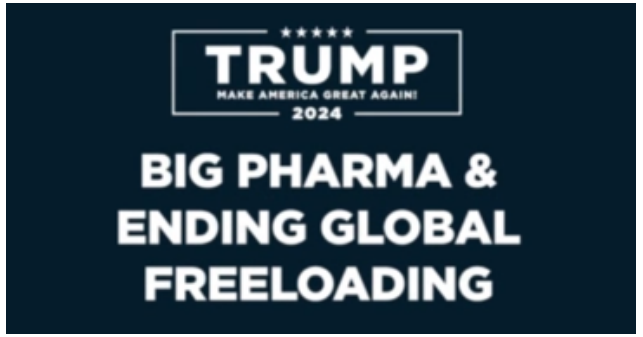
Donald J. Trump ✓
@realDonaldTrump

A “Favored Nations Clause” against Big Pharma, which I signed last week, means that the USA gets a price on Prescription Drugs that matches the price of the Country that pays the lowest price anywhere in the World. 50%, 60%, maybe 70% reduction. No other President would do this!

8:28 PM · Aug 22, 2020

Pres. Trump’s 2024 campaign website and a June 2023 campaign video indicate a high likelihood of reviving the international reference pricing concepts included in the Medicare Part B MFN Model





“*On Day One of my new term, I will sign an executive order to end this global freeloading on American consumers for once and for all.*”
“Under my policy, the United States government will tell Big Pharma that we will only pay the best price they offer to foreign nations, who have been taking advantage of us for so long – the United States is tired of getting ripped off

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Recap: Trump's Past International Reference Pricing Attempts

Oct. 25, 2018

- International Pricing Index (IPI) ANPRM released

IPI targeted 27 Part B drugs, would have based reimbursement on 126% of int'l prices and moved to a vendor-led system in lieu of buy-and-bill

Nov. 3, 2020

- *Election: Trump loses*

Nov. 20, 2020

- Most Favored Nation (MFN) Interim Final Rule released

MFN targeted 50 Part B drugs and would have based reimbursement on the lowest per capita GDP-adjusted price of any non-U.S. member country of the OECD

Dec. 28, 2020

- BIO v. Azar: Court granted a preliminary injunction – blocking the **MFN** from implementation (unless/until traditional rulemaking pursued)

Jan. 20, 2021

- *Biden sworn in*

Aug. 6, 2021

- CMS proposes to formally rescind the **MFN** Model

Dec. 27, 2021

- CMS rescinds the **MFN** Model in a final rule

- The threat of IRP began with the Trump administration's proposed IPI in 2018, as Trump sought to address "foreign freeloading," claiming manufacturers were "getting away with murder" and "giving bargain basement prices to other countries"
- Democrats continued the IRP focus with introduction of H.R. 3 in 2019 (limiting prices for 25+ drugs to 120% of ex-U.S. prices) and Pres. Biden's campaign platform
- Numerous reports released, including:
  - ASPE (Oct. 2018): U.S. pays 1.8x more than other countries for Part B drugs
  - GAO (March 2021): U.S. pharmacy benefit drug prices are 2 – 4x higher than other countries
  - RAND (Jan. 2021): U.S. drug net prices are 2.3x higher than other countries
  - ASPE (July 2022): U.S. prices were 256% of those in 32 comparison countries
  - RAND (Feb. 2024): U.S. prices were 278% of other countries' prices

- Agenda47, Protecting Americans by Taking on Big Pharma and Ending Global Freeloading (Trump video 6/23/2023):
  - "On Day One of my new term, I will sign an executive order to end this global freeloading on American consumers for once and for all."
  - "Under my policy, the United States government will tell Big Pharma that we will only pay the best price they offer to foreign nations, who have been taking advantage of us for so long – the United States is tired of getting ripped off."
- DonaldJTrump.com, Better Health Care Choices at Lower Costs (2024 campaign site):
  - "President Trump lowered drug prices for the first time in over 50 years and finalized the Most Favored Nation Rule to ensure that pharmaceutical companies offer the same discounts to the United States as they do to other nations."
  - "He will stop all COVID mandates and restore medical freedom, end surprise medical billing, increase fairness through price transparency, and further reduce the cost of prescription drugs and health insurance premiums."

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State Updates

Runoff Election Results

- Texas runoff elections were held two weeks ago, on May 28th.
- Nine house incumbents were at risk, and ultimately, only two were able to prevail:
  - Speaker Dade Phelan
  - Rep. Gary Van Deaver
- The Speaker now faces a challenge to his leadership position. Two others have officially announced, including Rep. Tom Oliverson, M.D., and Rep. Shelby Slawson.
- Of note is the loss of Rep. Stephanie Klick, who has been chair of the House Public Health Committee since 2021.

Political Winds

- There is a contingent of current and incoming Republicans who have signed a letter called “Contract for Texas.”
- The letter details 12 reforms that the Speaker of the House should adhere to in order to improve the integrity, transparency, and efficiency of the House. These include ending the practice of awarding Democrats with committee chairmanships, setting a 2-year term limit for the Speaker, and requiring a Republican Speaker Pro Tempore.
- A separate letter has been signed by 46 Republican House members, which commits them to only supporting a Speaker that will appoint Republicans as committee chairs.

Political Winds

- After openly supporting Speaker Phelan's opponent David Covey, Lt. Governor has continued his criticism of the Speaker's leadership.
- At the recent State GOP convention, the Lt. Gov said, "As lieutenant governor, I do not want to run the House, but I want a conservative Republican to be speaker who will run the House"
- Attorney General Paxton issued a warning to House Republicans who are considering supporting Speaker Phelan for an additional term.