



ADVI

TxSCO Update

Sept. 8, 2022



Overview: Notable Updates

Federal

- Surprise Billing
- Inflation Reduction Act

State

- Legislative hearing on health care workforce
- State general election updates

Federal Update



No Surprises Act: Timeline

December 27, 2020

- No Surprises Act (NSA) signed into law as part of the Consolidated Appropriations Act of 2021

July 2021

- The Departments released the [“Requirements Related to Surprise Billing; Part I,”](#) 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

October 2021

- 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

February 23, 2022

- The Eastern District of Texas in *Texas Medical Association, et al. v. United States Department of Health and Human Services* vacated portions of the October 2021 interim final rules related to payment determinations under the Federal IDR process. Specifically, a portion of the interim final rule that required arbiters to put an emphasis on choosing the amount closest to the QPA.

August 19, 2022

- The Departments issued final rules titled [“Requirements Related to Surprise Billing: Final Rules”](#). The 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 Qualifying Payment Amount (QPA)

HHS, Labor, and Treasury Release Final Rule and FAQs on the No Surprises Act Implementation



Aug. 19, 2022: HHS, Labor, and Treasury issued a [new final rule](#), [fact sheet](#), [status update](#), and a series of [frequently asked questions \(FAQs\)](#) regarding the implementation of the No Surprises Act (NSA).

“Downcoded” Definition

- Defined as either the alteration by a health plan of one service code to a lesser paid service code, or the addition, or removal of a modifier, if the changed code or modifier is associated with a lower Qualifying Payment Amount (QPA) than the service code billed by the provider, facility, or provider of air ambulance services

Payment Determinations Under the Federal IDR Process

- Providers cannot initiate the open negotiation period until after they have received an initial payment or payment denial
- Certified IDR entities must consider the QPA and then must consider all additional permissible information submitted by each party to determine which offer best reflects the appropriate out-of-network rate
 - The responsibility for monitoring the accuracy of plans’ and issuers’ QPA calculation methodologies with the Departments by requiring audits of plans’ and issuers’ QPA calculation methodologies
 - Plans and insurers that vary their contracted rates based on a provider specialty must calculate a median contracted rate separately for each specialty
 - This calculation is required when there is a material difference in the median contracted rates between different specialties, after accounting for variables other than specialty
- The certified IDR entity should also evaluate any information to avoid double counting information that is already accounted for by the QPA or any of the other information submitted by the parties
- **Arbiters must consider along with the QPA other permissible factors, including a facility’s teaching status, case mix, and scope of services, when determining the payment amount for an out-of-network service**
- A written decision is required that includes an explanation of the information that the certified IDR entity determined demonstrated that the selected offer is the out-of-network rate that best represents the value of the item or service
 - This includes the weight given to the QPA and any additional credible information regarding the relevant factors

Federal IDR Status Update



Aug. 19, 2022: The Departments also released a [status update](#) on the Independent Dispute Resolution (IDR) Process

High Volume of Disputes

- Between April 15, 2022, and August 11, 2022, disputing parties initiated over 46,000 disputes through the federal IDR portal
 - This is substantially more than the departments had estimated
- Certified IDR entities rendered a payment determination in over 1,200 disputes
- Non-initiating parties challenged over 21,000 disputes' eligibility for the federal IDR process, which constitutes nearly half of all disputes initiated
 - This means that a party has challenged the eligibility of a dispute and that additional review by the certified IDR entities is necessary to determine eligibility
- As a result of eligibility changes, preliminary data suggests that certified IDR entities have already found over 7,000 disputes ineligible for the IDR process

Complexity of Disputes

- The primary cause of delays is the complexity of determining whether disputes are eligible for the federal IDR process
- Eligibility relies on multiple factors including:
 - State/federal jurisdiction
 - Correct batching and bundling
 - Compliance with applicable time periods
 - Completion of open negotiations
- Eligibility reviews are processed more quickly when both parties provide all of the required information



No Surprises Act: Stakeholder Reaction

Insurers

- **AHIP:** AHIP noted that they appreciate that the Biden Administration's revised surprised billing rule continues to prioritize the QPA, but still worries that providers try to use the IDR Process to "game the system"
- **Coalition Against Surprise Medical Billing (also a patient/employer group):** *"We are concerned that changes to how arbitration entities are directed to consider various factors in making their determinations may lead to an inefficient and ineffective arbitration process. We are hopeful that as this law is implemented, arbitration will be used sparingly and as a backstop and that lower costs for patients remain the priority."*

Providers

- The **American Hospital Association** and the **American Medical Association** have not publicly responded to the rule
- **American College of Emergency Physicians:** "ACEP is pleased that the final rule specifies the QPA will no longer be the presumptive factor. Less favorably, the rule claims that some additional factors, such as patient acuity, could already be reflected in the QPA, and therefore allows IDR arbitrators to omit them from consideration when choosing the proper payment amount."
- **Federation of American Hospitals:** "This moves more in the direction of the original intent of the legislation"

Patient Groups

- **The American Heart Association:** The final rule "marks a critical point in the fight to end the most egregious surprise medical bills."
- **Families USA:** "Today, they have laid out a key piece of the puzzle for getting costs under control: critical guardrails that help ensure fair payment to providers while discouraging abuse of the reimbursement negotiations process"

Inflation Reduction Act: Key Takeaways



Key takeaways for the drug pricing policies included in [H.R. 5376](#), the Inflation Reduction Act:

Government “Negotiation”

- While referred to as government “negotiation,” the policy equates to government price setting
 - Manufacturers have no leverage: either accept the government’s price or face a 95% excise tax on all U.S. sales for the drug
- The government’s price applies to the Medicare market specifically, with significant spillover implications for the commercial and Medicaid markets as well
- The number of drugs subject to the government’s price will compound annually:
 - Starting 2026, the government’s price initially applies to 10 drugs
 - This increases annually, reaching 100 drugs by 2031, and 200 drugs by 2036

Part D Benefit Redesign

- Pharmacy benefit drugs will be more affordable for Medicare Part D patients with a \$2,000 out-of-pocket max
- Manufacturers required to provide greater discounts throughout all phases of the Part D benefit design

Inflationary Penalties

- The bill limits manufacturers’ ability to raise prices faster than inflation

Insulin Copay Cap for Medicare

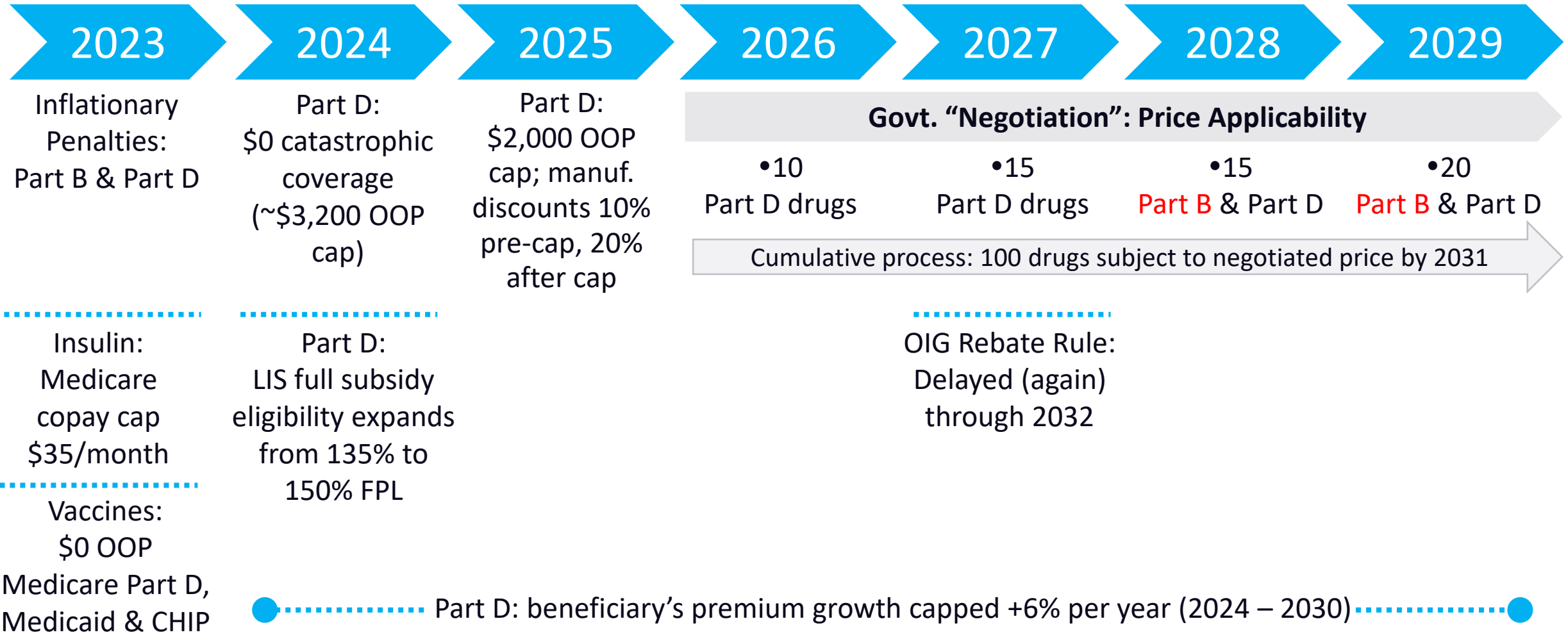
- Establishes a \$35 copay cap for Medicare Part B and Part D insulin

Enacted Aug. 16

TxSCO: significant Part B, commercial and Medicaid reimbursement implications for targeted physician-administered drugs

TxSCO: helpful for cancer patients

Inflation Reduction Act Implementation



“Inflation Reduction Act”: Key Implications



Key Implications		Policy Driver		
		Govt Negotiation	Inflationary Penalties	Part D Redesign
Pricing	<ul style="list-style-type: none"> Higher launch prices <ul style="list-style-type: none"> Resulting in higher patient out-of-pocket costs 	✓	✓	
	<ul style="list-style-type: none"> Price increases aligned with, or just below, inflation <ul style="list-style-type: none"> Caveat: could see prices increase faster than inflation for products with higher commercial utilization than Medicare (as penalties apply to Medicare units only) 		✓	
Innovation	<ul style="list-style-type: none"> Fewer drugs to launch in future 	✓		
	<ul style="list-style-type: none"> Little (or no) incentive to pursue new indications <ul style="list-style-type: none"> Potential delays to market for FDA approval for larger, earlier stage disease Greater off-label use, resulting in increased provider burden and Part B coverage risks 	✓		
Competitive Landscape	<ul style="list-style-type: none"> Biosimilar and generic market outlook is a mixed bag: <ul style="list-style-type: none"> Potentially “decimated”: biosimilar and generic versions of a selected drug would be expected to launch at a price that is significantly lower than the selected drug’s MFP (which would already be a steeply discounted price) Alternatively, potential opportunity if innovator/brand manufacturers can avoid negotiation by entering into volume-limited agreements with biosimilar/generic manufacturers 	✓		
Providers	<ul style="list-style-type: none"> Provider reimbursement cuts for targeted physician-administered drugs <ul style="list-style-type: none"> Possibly resulting in increased provider vertical integration, consolidation 	✓		
	<ul style="list-style-type: none"> In-office prescribing at risk <ul style="list-style-type: none"> Part D Plans/PBMs more motivated to force patients to their own specialty pharmacy 			✓
Plans & PBMs	<ul style="list-style-type: none"> Greater Part D Plan consolidation as smaller plans may not be able to be able to compete with new 60% reinsurance liability 			✓
	<ul style="list-style-type: none"> More formulary exclusions, increased utilization management (UM) Part D Protected Class drugs remain “protected,” but plans likely to be more aggressive with UM 	✓		✓
	<ul style="list-style-type: none"> Potential incentive to disadvantage selected drugs on formulary (if PBMs favor high rebates over lowest list price) 	✓		
Patients	<ul style="list-style-type: none"> Improved affordability and adherence for Part D drugs 			✓
	<ul style="list-style-type: none"> Reduced need for manufacturers’ Patient Assistance Programs (PAPs) 			✓
	<ul style="list-style-type: none"> Fewer Part D Plan options to choose from 			✓
	<ul style="list-style-type: none"> Lower cost-sharing for selected drugs, as cost-sharing tied to the MFP 	✓		

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Government Negotiation: Part B Drug Implications



Manufacturers must offer the MFP to providers on behalf of Part B beneficiaries

Medicare reimburses providers at 106% MFP for Part B beneficiaries (reduced add-on revenue)

Medicare sales at the MFP are included ASP and Best Price, but excluded from AMP

Once "selected" (subject to MFP), remain selected until first year that begins >9 months after competition is marketed

When no longer "selected," Medicare reimbursement returns to ASP + 6%

Medicare

- Manufacturers **must** offer the steeply discounted "negotiated" price (MFP) to providers on behalf of all Medicare patients; providers are reimbursed at MFP + 6%

Commercial

- Manufacturers **may** be forced to offer the MFP to providers on behalf of commercial payer patients because the policy results in one of the following scenarios →

Medicaid

- Manufacturers **may** be forced to offer the MFP to providers on behalf of Medicaid* patients because the policy results in one of the following scenarios →
- Medicaid rebates may increase:
 - Medicare sales at the negotiated price (MFP) are included in the calculation for Best Price, but excluded from AMP, possibly resulting in higher Medicaid rebate liability
 - Unit Rebate Amount (URA) for innovator drugs: the greater of 23.1% of AMP per unit or the difference between the AMP and the Best Price per unit and adjusted by CPI-U based on launch date and the current quarter AMP

340B

- Manufacturers must offer 340B providers the lower of: MFP or 340B ceiling price
- Whether the MFP or 340B ceiling price is lower will vary by drug
 - 340B ceiling price = AMP minus the URA

Implications for ASP-based reimbursement

- In addition to Medicare patient applicability, the MFP will very likely apply for reimbursement on behalf of commercial and Medicaid patients due to the MFP's impact on ASP-based reimbursement
- **Scenario 1:** Providers can't afford to purchase the drug, because the purchase price is higher than commercial payers' ASP-based reimbursement (since Medicare sales at the MFP are included in the ASP calculation, ASP will drop)
- **Scenario 2:** Providers can afford to purchase the drug, but only because manufacturers give steep enough discounts so that the purchase price for commercial and Medicaid patients is the same as the Medicare MFP (i.e., ASP = MFP)
- **Scenario 3:** Commercial payers and providers renegotiate their contracts so that targeted physician-administered drugs are reimbursed based on a non-ASP-related formula, allowing manufacturers charge a price higher than the MFP for non-Medicare patients (ADVI's payer advisors say this is unlikely)
- Next Steps: Providers advocated for a [rebate approach](#) to prevent ASP implications; expect for these efforts to continue before price applicability for Part B drugs begins in 2028

MedPAC September Meeting: Part B Spending in Context

Price has been the largest driver of Part B drug spending growth

	Part B
Spending in 2020:	<ul style="list-style-type: none">• \$40.7 billion*
Spending growth from 2009-2020:	<ul style="list-style-type: none">• Over 9 percent per year on average
Largest driver of the spending growth from 2009-2020:	<ul style="list-style-type: none">• Growth in average price per Part B drug, which reflects post-launch price growth; launch of new, higher-priced products; and shifts in mix of drugs
Spending is highly concentrated:	<ul style="list-style-type: none">• 20 products account for 52% of spending• Examples of indications of top products: cancer, macular degeneration, inflammatory conditions

MedPAC September Meeting: “Addressing high prices of drugs covered under Medicare Part B”

MedPAC staff [presented](#) three policy approaches regarding payment for Part B drugs.

Option 1 targets Accelerated Approval Part B drugs, while Options 2 and 3 target at all Part B drugs.

Option 1

Set a cap on payment for Part B drugs with “uncertain clinical benefit” until post-marketing trial confirms drug’s clinical benefit

- Until a confirmatory trial shows clinical benefit, Medicare could cap drug payment based on one of the following:
 - Accelerated approval (AA) drug’s estimated net clinical benefit and cost relative to standard of care
 - Some increment of the payment rate for the standard of care
 - 106% of the AA drug’s ASP for 3 years and then cap payment based on the standard of care
- An alternate option is for Medicare to establish rebates based on a percentage of AA drug’s ASP if confirmatory trials are not completed or have negative results
- Commissioners Chernew, Dusetzina, and Navathe noted that reforms to accelerated approval should be made cautiously

Option 2

Apply reference pricing to Part B drugs with similar health effects that treat a given condition

- Very similar to “Least Costly Alternative”
- Each product in a group would remain in its own billing code
- Medicare would set a payment rate for a group of drugs with similar health effects based on one of the following:
 - Lowest ASP of product in reference group (i.e., least costly alternative)
 - Volume-weighted ASPs of all products in reference group
 - Lower of the volume-weighted ASPs of all products in reference group or the ASP of the specific product furnished
- Includes process for an exceptions process and for how groups are established
- Commissioner Sarran, Gelb Safran, Navathe, and Casalino expressed support for Option 2

Option 3

Modify ASP add-on payment

- Add-on equals the lesser of 6%, 3%+\$21, or \$175 per drug per day
- This approach:
 - Converts a portion of the percent add-on to a fixed fee (3%+\$21)
 - Caps add-on for lower priced drugs (6%) and high-priced drugs (\$175)
- Commissioners Dusetzina, Sarran, Poulsen, Navathe and Casalino expressed support for Option 3
- *See next slide for more details*

MedPAC plans to vote on these options in future meetings

MedPAC September Meeting: Option 3 Example Calculations

Add-on amounts for differently priced drugs under current policy and policy option

ASP per drug admin.	Current policy 6%	Option Lesser of: (6%, 3% + \$21, \$175)
\$5	\$0.30	\$0.30
100	6	6
700	42	42
1,000	60	51
3,000	180	111
5,000	300	171
15,000	900	175

- Add-on reduced for drugs with ASP per administration > \$700
- Reduces differences in add-on payments
 - For \$1,000 vs \$3,000 drug, add-on difference is \$120 (current policy) and \$60 (policy option)
 - Largest reduction for highest priced products (e.g., \$5,000 vs. \$15,000 drug)

Note: "ASP per drug admin." refers to ASP per drug administered and is defined as a drug's ASP unit price times the number of units of the drug administered to the patient on a particular day. For drugs furnished by suppliers (e.g., nebulizer drugs and certain oral drugs), it refers to ASP per prescription. ASP and add-on payments reflect payment amounts before the sequester. Data are preliminary and subject to change.

State Update

Health Care Workforce

- On August 23rd, the Senate Committee on Health and Human Service met in a public hearing to:
 - Study the impact of the global pandemic on the health care workforce in acute and long-term care;
 - Identify health care staffing challenges and examine how staffing services and payment models changed the economics of the health care workforce; and
 - Identify and recommend ways to increase the health care workforce pipeline.

Health Care Workforce Data

- DSHS does not have data that includes COVID impacts because of the timing of their study
- RN and nurse practitioner shortage will be 57,000 by 2032
- For every 1 nurse looking for a job, there are 3 open positions
- Concern from committee that vaccine and mask mandates led to loss in health care workforce

Health Care Workforce

- Texas Student Financial Aid Programs
 - Testimony from the Texas Higher Education Coordinating Board indicated that there are several programs that are not sufficiently funded or are overprescribed. There are also limitations related to how these funds are spent and allocated.
- Texas Board of Nursing
 - In 2021, there were 3,500 applicants for nursing licenses, which is a large increase
 - Barriers to new nurses include faculty shortages and clinical space availability
 - Increased clinical space for nursing students can be expanded to consortiums that work together to find every space available and assign students accordingly
- Texas Hospital Association
 - Expanding capacity required recruitment and retention bonuses, salary increases, and increased benefits
 - Data shows workforce costs in 2022 are up 33% since the start of the pandemic
 - Legislature should pass policies that find & employ faculty and increase clinical space
 - Over 15,000 candidates were turned away from Texas nursing schools

General Election Updates

- Statewide Races
 - The Governor's race is heating up as Beto O'Rourke takes aim at Governor Abbott on a variety of issues, including rural community needs, reproductive rights, school safety and gun control. O'Rourke is traveling the state and seems to be drumming up support in rural communities typically ignored by statewide candidates
 - The Lieutenant Governor's race is also experiencing movement as Dan Patrick embarks on a bus tour of the state. Some polling data suggests that his race with Democrat Mike Collier is close. Outgoing Republican Senator Kel Seliger and outgoing Republican Tarrant County Judge Glen Whitley each came out in support of Collier; earlier this week outgoing Democratic Senator Eddie Lucio gave a sound endorsement of Dan Patrick.
 - In the race for Attorney General, most polls indicate this race being the closest out of the top three statewide races.
 - Interestingly, in the Gov and Lt Gov race, both incumbents have engaged with their opposition in the media which is typically not seen this early in a general election race, particularly from the two most established and powerful incumbents in the state. This can be and likely is a signal that the races are polling closer than either incumbent is comfortable with.



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