TxSCO Update

June 8, 2023

Overview: Notable Updates

Federal

- In-office dispensers and mail order drugs
- Site neutral payment provision advances to House floor
- Merck files lawsuit challenging IRA
- EOM: the latest

State

- Updated Medicaid unwinding estimates and state survey responses
- Legislative Update
- Budget Update

Federal Update

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In-Office Dispensing: Mail-Order Prescriptions

March 2020:
- 3/30: CMS issued blanket waivers of sanctions under the physician self-referral law for COVID-19 Purposes.

Sept. 2021:
- CMS issued an FAQ related to the blanket waivers that suggests **mail-order prescription drugs** could violate the Stark Law once the waivers expire (when the PHE ends).
- COA believes that CMS' interpretation could also be used to prohibit a spouse or any caregiver from picking up a patient's drug(s) from the patient's medical practice.

May 2023:
- 5/11: PHE ends, along with the blanket waivers.
- 5/19: CMS issued an FAQ reiterating their position that **mail-order prescription drugs** violate the Stark law given that the PHE waivers have expired.
  - CMS stated that this is their "long-standing" position and that they do not anticipate harms to patient access (but will be monitoring).
  - CMS also noted that any changes would need to occur through notice and comment rulemaking.

What can practices do when the blanket waivers expire?

- Utilize the VBE exception if practical
- Require patients to pick up medications in person or
- Refer them to third-party mail-order pharmacies

Value-Based Enterprise (VBE) Exception

- There is a Value-Based Enterprise (VBE) exception that may provide a Stark Law exception for practices that mail medications, so long as they meet applicable criteria.
- The exception requires practices to be in an arrangement with full financial downside risk, partial downside risk, or no downside risk but engaging in value-based activities.
  - Practices not already engaged in a value-based arrangement may need to substantially alter their business practices to do so.

References
COA letter to HHS (April 4, 2023)
OBR article (May 8, 2023)
Congressional sign-on letter from bipartisan group of 54 members to HHS urging CMS to retract the FAQ language (April 8, 2023)

House E&C Committee Advances PBM, Prescription Drug Proposals to House Floor

On May 24, 2023, the House Energy and Commerce Committee advanced 5 health-related bills to the House floor, including H.R.3561, the PATIENT Act.

Topic	Summary of provisions in the PATIENT Act (H.R.3561)	Adapted From
PBMs	Requires PBMs to report annually to health plan sponsors on information, including: • Acquisition cost of drugs • Total out-of-pocket spending • Formulary placement rationale • Aggregate rebate information Requires health plans and PBMs to send regular reports to GAO. Directs GAO to submit a report to Congress on the practices of group health plans' pharmacy networks	H.R. 2679, **PBM Accountability Act**
Medicaid	• Prohibits spread-pricing and requires pass-through pricing models for PBMs in Medicaid. • Require state contracts with Medicaid managed care contractors to limit drug reimbursement to ingredient cost plus a dispensing fee. • Requires HHS to submit a report to Congress on Medicaid specialty drug coverage and reimbursement	H.R. 1613, **Drug Price Transparency in Medicaid Act of 2023**
Site Neutral Payment	• Requires Medicare to pay the same amount for drug administration in outpatient hospital departments and physician office settings, phased in and fully effective 2028.	
Cost-Sharing	• Requires insurers to cap cost sharing for highly rebated drugs at the price the insurer pays for the drug.	H.R.3285, **Fairness for Patient Medications Act**
Transparency	• Codifies transparency requirements for hospitals and insurers, including requiring disclosure of the average negotiated rate and acquisition cost for drugs.	H.R. 2691, **Transparent PRICE Act**

H.R.3561 advanced 49-0, however some Democrats (Reps Tonko (NY-D) and Clarke (NY-D)) raised concerns with the site neutral payment provision, signaling that broader site neutral reforms that were left out of the packing may face barriers in the full House and Senate.

Source: Markup (5/24/23, link); Health Bills Advanced (5/24/23, link)

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Ownership Transparency	Requires certain physician practices and hospitals that change ownership to report that information to CMS. Requires HHS to issue annual reports on trends in healthcare consolidation.	H.R. 3262, __
	Requires MA and Part D plans to report data on interactions with healthcare providers they share common ownership with (including physician groups, PBMs, and pharmacies) compared with those they do not. Required information includes: • Negotiated prices for Part D drugs • DIR fees for in- and out-of-network pharmacies • Total pharmacy and manufacturer rebates collected by PBM and passed through to health plan	H.R. 3282, **Promoting Transparency and Healthy Competition in Medicare Act**
Other	Requires each hospital outpatient department to include a unique identification number on Medicare claims.	H.R. 3237, __
	Require the FDA to identify and disclose inactive ingredients to generic drugmakers upon submission of an ANDA.	
	Requires diagnostic laboratories to post the prices of their tests and services.	H.R. 3248, **Diagnostic Lab Testing Transparency Act**
	Postpones cuts to Medicaid disproportionate share hospital payments for 2 years.	H.R.2665, **Supporting Safety Net Hospitals Act**
	Funding for community health centers, teaching health center graduate medical education, the National Health Service Corps and special diabetes programs	

Source: Markup (5/24/23, link); Health Bills Advanced (5/24/23, link)

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Advanced with mainly GOP support	
H.R. 3290, __	Requires hospitals participating in 340B to provide information about how funds from drug discounts were used.
H.R. 2666, **Medicaid VBPs for Patients (MVP) Act**	Codifies the use of value-based purchasing (VBP) arrangements in Medicaid and implements VBP-related price reforms, such as allowing multiple best price points for manufactures subject to a VBP arrangement.
Advanced with bipartisan support	
H.R. 3284, **Providers and Payers COMPETE Act**	Requires the HHS Secretary to consider the effect of regulatory changes on provider and payer consolidation. Requires an annual report.
H.R. 2544, **Securing the U.S. Organ Procurement and Transplantation Network Act**	Makes updates to the Organ Procurement and Transplantation Network.

- Democrats argued that hospital requirements should be paired with 340B contract pharmacy requirements for drug manufacturers.

- There was significant Democratic opposition to H.R.2666, the Medicaid VBP for Patient (MVP) Act.
- Ranking Member Pallone (D-NJ) stated that he intends to encourage the Biden administration to repeal the Trump era regulations the bill would codify.

Source: Markup (5/24/23, link); Health Bills Advanced (5/24/23, link)

TxSCO Takeaway: if Merck successful, we avoid physician drug reimbursement issues starting 2028

Merck files lawsuit to halt IRA government negotiation

Overview

- On June 6, 2023, Merck filed a lawsuit challenging the Inflation Reduction Act's provision that allows Medicare to negotiate drug prices and set a "Maximum Fair Price", considered by industry to be price-setting
- The lawsuit names HHS, CMS, HHS Sec. Becerra, and CMS Administrator Brooks-LaSure

IRA Challenges

- Industry lobbyists and lawyers signaled last month that pharmaceutical manufacturers were preparing to sue
- Many expected filings to occur after publication of the final guidance (anticipated in July) or the IPAY 2026 Selected Drugs (Sep. 1)

Arguments

- Violates the 5th amendment (Takings Clause)
  - Merck would be forced to provide products at government-set prices
  - Govt is prohibited from taking private property for public use without just compensation
- Violates the 1st amendment
  - Merck would be forced to sign an agreement it does not agree with
- IRA provides no way for Merck to avoid its scheme of forced sales and compelled speech

Merck will be compelled, under threat of eight-figure daily excise-tax penalties, to sign an agreement submitting to forced sales of Januvia by October 1, 2023. Yet the IRA delays a manufacturer's ability to terminate its Medicare Part D agreements for between 11 and 23 months. 42 U.S.C. § 1395w–114a(b)(4)(B)(ii). To avoid being penalized for failure to sign the October 1, 2023, "agreement," Merck would therefore have needed to terminate all relevant Medicare contracts by January 31, 2022—*months before the IRA was even enacted*. Of course, Merck could not have known to do so. That reality confirms that the IRA imposes mandates, not "conditions."

Recap Industry sources previously identified the following as likely targets for legal challenges:

Rules that forbid manufacturers from discussing negotiations and impose a $1 million fine per day.

- May be challenged under the Constitution's 1st (freedom of speech) and 8th (protection against excessive fines) amendments.

Lack of formal rulemaking process for initial government negotiation guidance.

Factors describing whether a drug is considered eligible for negotiation.

- Sources argue that:
  - The definition of a single-source drug sets too high a bar for competition.
  - These provisions may contradict legislation and unlawfully extend the IRA.

Drug companies may file for emergency injunctions to delay government negotiation.

"Three industry lobbyists and lawyers said that unless Medicare changes its proposals before it finalizes them in July, drugmakers will likely file lawsuits arguing that the agency is not complying with Biden's legislation nor the U.S. Constitution." Source: Reuters (5/9/2023, link)

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Source: NY Times (link); Merck filing (link)

EOM Update

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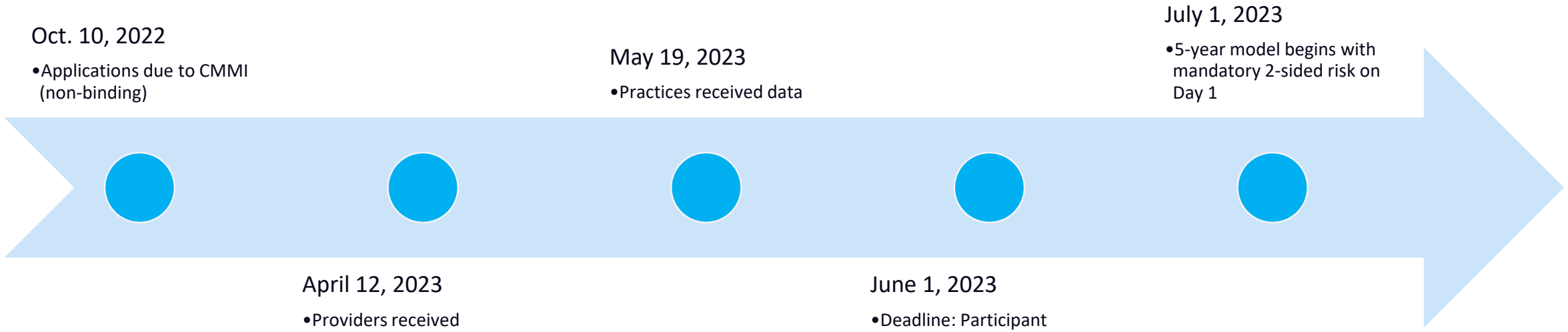
Recap on EOM Design: EOM Draws from OCM Foundation with Some Modifications

Narrower than OCM	Same as OCM	Broader than OCM

• Fewer eligible patients
  • Limited to 7 tumor types (breast cancer, chronic leukemia, small intestine/colorectal cancer, lung cancer, lymphoma, multiple myeloma, and prostate cancer)
  • Hormonal therapy (exclusively) excluded
• MEOS* (monthly payment) lowered from $160 to:
  • $70 (non-duals)
  • $100 (duals)
• Downside risk required on Day 1
	• Voluntary
	• Chemotherapy trigger to 6-month episode measuring total cost of care
	  • MEOS plus performance structure
	• **Patient navigators remain**
	• Multi-payer model
	• CAR-T excluded
	• Part B/D drug reimbursement remains according to current policy (e.g., ASP+6% or via Part D)
		• Adopts OCM's 6 redesign activities and adds 2 more:
		  • ePROs (gradual phase-in)
		  • screening beneficiary social needs using HRSN* tool
		• Fixes OCM's attribution issues
		  • More logical approach, as the initial treating practice is attributed so long as they have 25% of cancer claims
		• Novel Therapy Adjustment (NTA) will be calculated separately for each of the 7 cancer types
		  • OCM NTA calculated in aggregate across all cancer types

HRSN: health-related social needs
MEOS: Monthly Enhanced Oncology Services payment for Enhanced Services provided to eligible beneficiaries

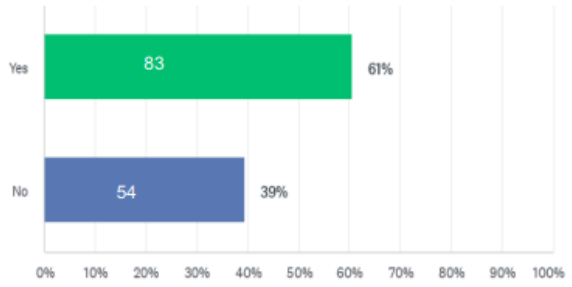
EOM Timeline



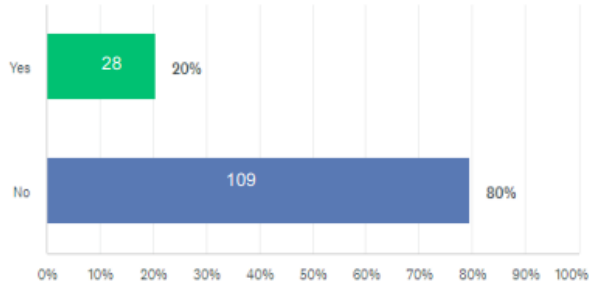
COA Survey (conducted May 1-19): Expectations on EOM Participation: 40 Practices

OCM Experience

Did you participate in the OCM?

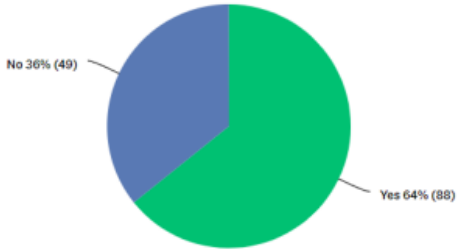


Were you ever in two-sided risk in the OCM?

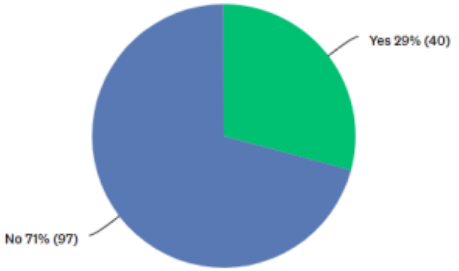


EOM Participation

Did you submit a letter of Intent to Participate?



Are you currently planning to participate in the EOM?



Source: COA Survey: EOM Yes or No 6/6/2023 (link)

What is influencing practices as they make EOM participation decisions?

In

- Position your team to participate in value-based care models with other payers
- Your team wants to be a leader in payment reform
- Your team was financially successful in the OCM and expects the same in EOM

Out

- EOM is too unpredictable
- Immediate entry into a two-sided risk arrangement
- The MEOS is too low
- Unpredictability of drug prices

Ideas

- Increase transparency related to episode target prices
- Improve the time to receive CMMI feedback reports
- Make two-sided risk optional or phase it in

Source: COA Survey: EOM Yes or No 6/6/2023 (link)

Medicaid Unwinding

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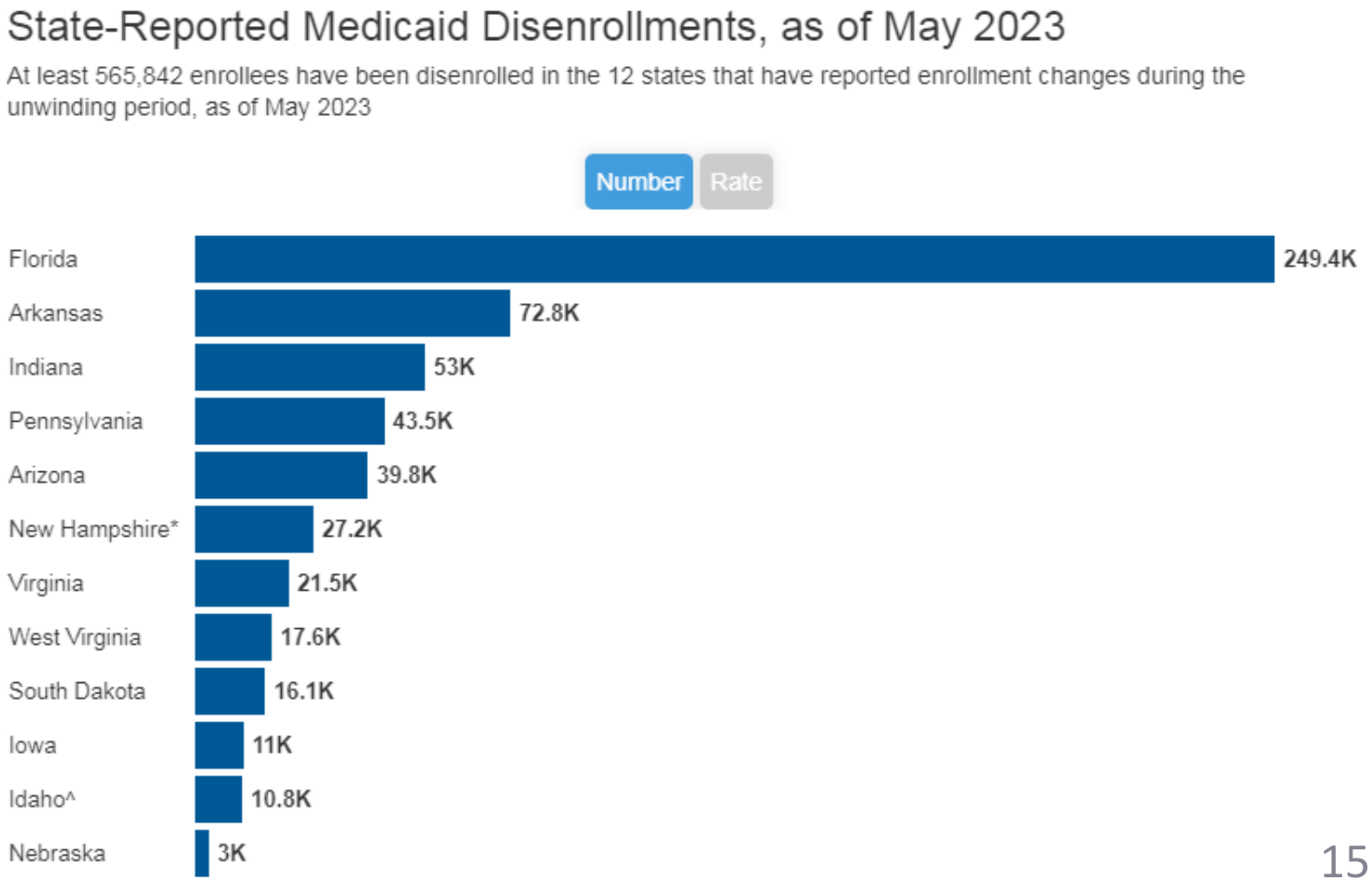
Medicaid Unwinding: Updated Estimates

Early data show wide variation in disenrollment rates. Data from 12 states show that over half a million enrollees have been disenrolled. The disenrollment rate ranges from 54% to 10%, with a median of 34.5%.

States' methods for prioritizing renewals may be driving early differences in disenrollment rates

- In some states (AR, ID, IA, FL), early renewals are focused on people the state no longer thinks are eligible, which may drive higher disenrollment rates initially
- Other states conduct renewals based on an individual's renewal date or use a combination of the two

Other factors, such as program capacity and communication and outreach efforts, may also drive state variation.



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Source: KFF (5/31/23, link)

KFF

Medicaid Unwinding: Updated Estimates

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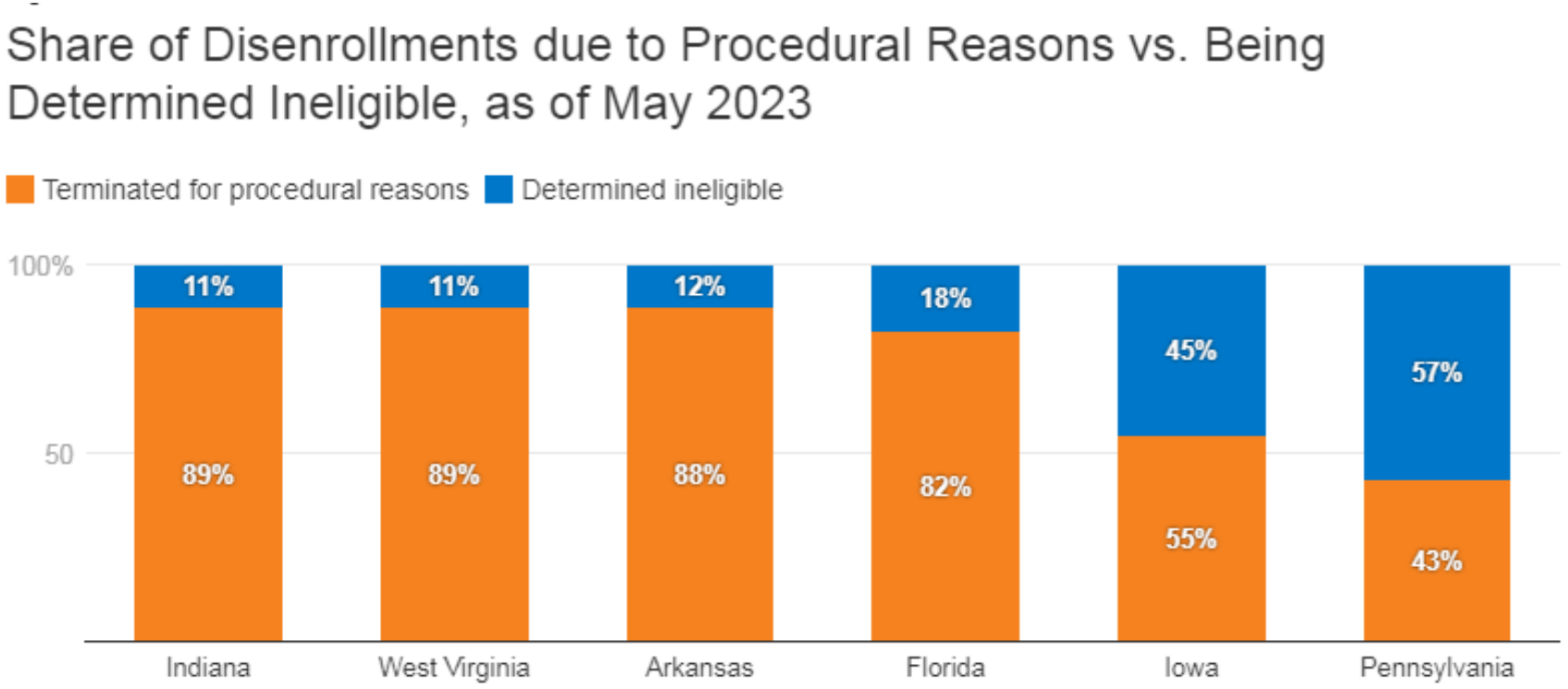
- Survey findings indicate that nearly two-thirds of current enrollees have not had a change of income or circumstance in the past year that would make them ineligible for Medicaid.
- This suggests that many of the individuals terminated for procedural reasons may still be eligible.

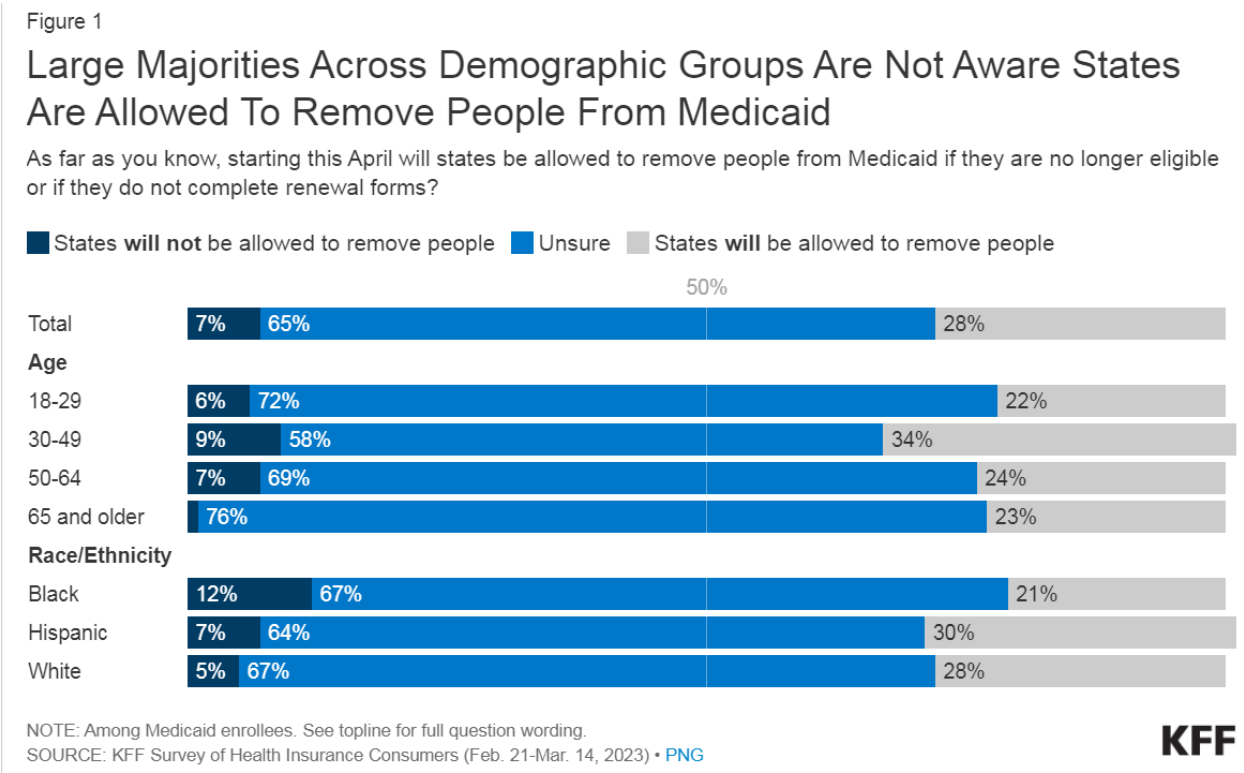


Source: KFF (5/31/23, link)

Recent KFF Survey Shows Concerning Trends in Medicaid Redeterminations Among Beneficiaries

Key Findings

- Most Medicaid enrollees are not aware that state Medicaid programs are allowed to disenroll beneficiaries
- Almost half of Medicaid beneficiaries surveyed say that they have not previously been through a coverage renewal process
- Beneficiary contact information may not be up to date and mode of renewal may impact who receives process information
- Four in ten say they would not know where to look for coverage if they were disenrolled in Medicaid and could be uninsured



Source: KFF Survey (link)

State Update

88th Legislative Session Wrap Up

- The Texas Legislature wrapped up its 88th Regular Session on May 29 after a 140 day session
- A total of 8,046 House and Senate bills were filed with only 1,246 passing – a 15.48% pass rate
  - Almost 1,000 more bills than the last legislature filed and 200 more than the last legislature passed – 15.49% pass rate
- Public school finance, school choice, and property tax relief were slated to be major issues and none were ultimately passed
- Several bills addressing the electric grid did pass
- The Gov has called a special session that is ongoing to address property tax relief and more special sessions are expected as deliberations continue.
- This legislature made history at least twice
  - They expelled a fellow member for allegedly having had an inappropriate relationship with a staffer
  - They passed articles of impeachment against a statewide elected official - Attorney General Ken Paxton

88th Legislature Constitutional Amendments

- HJR 2 (Bonnen | et al.) Proposing a constitutional amendment authorizing the 88th Legislature to provide a cost-of-living adjustment to certain annuitants of the Teacher Retirement System of Texas
- HJR 3 (Bonnen) Proposing a constitutional amendment relating to the Texas University Fund, which provides funding to certain institutions of higher education to achieve national prominence as major research universities and drive the state economy
- HJR 107 (Price | et al.) Proposing a constitutional amendment to increase the mandatory age of retirement for state justices and judges
- HJR 125 (Ashby | et al.) Proposing a constitutional amendment creating the broadband infrastructure fund to expand high -speed broadband access and assist in the financing of connectivity projects
- HJR 126 (Burns | et al.) Proposing a constitutional amendment protecting the right to engage in farming, ranching, timber production, horticulture, and wildlife management
- HJR 132 (Hefner | et al.) Proposing a constitutional amendment prohibiting the imposition of an individual net worth or wealth tax
- HJR 134 (Bonnen | et al.) Proposing a constitutional amendment to abolish the office of county treasurer of Galveston County
- SJR 64 (West | et al.) Proposing a constitutional amendment authorizing a local option exemption from ad valorem taxation by a county or municipality of all or part of the appraised value of real property used to operate a child-care facility
- SJR 74 (Parker | et al.) Proposing a constitutional amendment providing for the creation of the centennial parks conservation fund
- SJR 75 (Perry | et al.) Proposing a constitutional amendment creating the Texas water fund to assist in financing water projects in this state
- SJR 87 (Huffman | et al.) Proposing a constitutional amendment to authorize the legislature to exempt from ad valorem taxation equipment or inventory held by a manufacturer of medical or biomedical products to protect the Texas healthcare network and strengthen our medical supply chain
- SJR 93 (Schwertner) Proposing a constitutional amendment providing for the creation of the Texas energy fund to support the construction, maintenance, modernization, and operation of electric generating facilities

88th Legislature - Bills of Interest

Bills that passed

- **HB 12** – Provides 12 month Medicaid eligibility for new mothers.
- **HB 25** – Creates a Canadian drug wholesale importation program.
- **HB 44** - Removes state health funding, including Medicaid and CHIP funding, if a health provider declines to serve a potential patient because of refusal or failure to obtain certain immunizations or vaccines. Still allows providers to require immunization as long as the provider allows for certain exemptions. Does not apply to providers who specialize in oncology or organ transplant.
- **HB 711** - Prohibits certain "anticompetitive" contracting terms in health care such as anti-tiering clauses, gag clauses, and most-favored nation clauses.
- **HB 755** - Prohibits health plans from requiring more than one authorization in a 12 month period for autoimmune diseases, hemophilia or Von Willibrand disease.
- **HB 999** - Prohibits the use of copay accumulator programs in most instances.
- **HB 1283** - Extends the single statewide drug formulary and preferred drug list for Medicaid until 2033.
- **HB 1592** – Applies existing balance billing protections to self-funded and fully-insured ERISA plans.
- **HB 1647** - Prohibits whitebagging mandates for clinician administered drugs in a physician office setting.
- **HB 1649** - Provides for mandated health plan coverage for fertility preservation but does not include the storage of unfertilized eggs. Also includes a notice requirement for facilities who provide chemotherapy radiation procedures to notify parents that the procedure could impair the fertility of their child.

88th Legislature - Bills of Interest

Bills that passed

- **HB 2002** - Requires that any out of pocket costs borne by patients be counted toward their deductible and out of pocket maximum regardless of whether or not they used their insurance.
- **HB 3286** - Makes changes to the Texas Vendor Drug Program including new exceptions to the preferred drug list, changes to preferred status for non-reviewed drugs, and other minor changes.
- **HB 4500** - Requires health plans to make available to physicians a website through which they can determine coverage and cost sharing responsibilities for their patients.
- **SB 25** - Expands the current nursing loan repayment program to nurses working part time, allows the THECB to increase the existing $7,000 annual cap per nurse and re-establishes the program until 2027.
- **SB 401** - Prohibits medical staffing agencies from charging exorbitant or excessive prices during a declared state of disaster.
- **SB 490** - Requires health care providers to send an itemized bill prior to attempting to collect and money from a patient.
- **SB 739**– Establishes October 10 as Supportive Palliative Care Awareness Day
- **SB 773** - Provides patients with severe chronic conditions, as determined by HHSC, access to investigational treatments that have passed Phase 1 clinical trials in certain circumstances with physician determination that other treatments are unlikely to provide relief or are unavailable.
- **SB 989** - Provides required coverage for certain biomarker testing that provides clinical utility.

88th Legislature - Bills of Interest

Bills that failed

- **HB 118** – Prohibits health plans from charging a premium, copayment, deductible, or other form of cost sharing for prostate cancer screening.
- **HB 173** – Creates a licensing program for genetic counselors.
- **HB 319** - Would have created liability protections for health care providers who chose not to participate in a procedure for reasons of conscience.
- **HB 536** - Would have tied liability limits for health care liability claims to the consumer price index (CPI).
- **HB 700** - Would have established a Texas-specific health insurance exchange to provide Texas marketplace plans.
- **HB 807** - Would have eliminated provisions allowing DSHS to determine appropriate immunizations for requirements related to public and higher education enrollment, thereby ceding control to the Legislature.
- **HB 826** - Would have prohibited non-medical switching and other changes to drug coverage within a plan year with certain exceptions.
- **HB 895** - Would have prohibited the use of extrapolation by health plans for completion of an audit and required that any recoupment be based on actual overpayments.
- **HB 1001** - Would have created an option for health plans to offer "mandate light" coverage under which only benefits required for ERS and TRS plans would be mandated.

88th Legislature - Bills of Interest

Bills that failed

- **HB 1026** - Would have required health plan coverage for hair prostheses for cancer patients.
- **HB 1236** - Would have created a “prudent layperson” standard for the determination of consideration of services as emergency services.
- **HB 1240** - Would have authorized a physician to provide or dispense drugs to the physician's patients and be reimbursed for the cost of providing or dispensing those drugs without obtaining a license to practice.
- **HB 1599** - Would have implemented an “express lane option” to improve access to Medicaid and CHIP health insurance for children who are already eligible but uninsured.
- **HB 1726** - Would have ensured health benefit plan issuers reimburse and pay claims for telemedicine medical services, teledentistry dental services, and telehealth services at the same rate as in-person visits.
- **HB 1805** - Would have expanded the Texas Compassionate Use program by increasing the level of THC in medical cannabis and expanding the program for additional patients.
- **HB 2414** - Would have allowed health insurers to incentivize the use of affiliated providers as long as they maintain a fiduciary responsibility to their patient.
- **HB 2556** - Would have created a medical license allowing certain medical school graduates to practice under supervision.
- **HB 2587** - Would have expanded the BCCS program to women at or below 250% FPL.

88th Legislature - Bills of Interest

Bills that failed

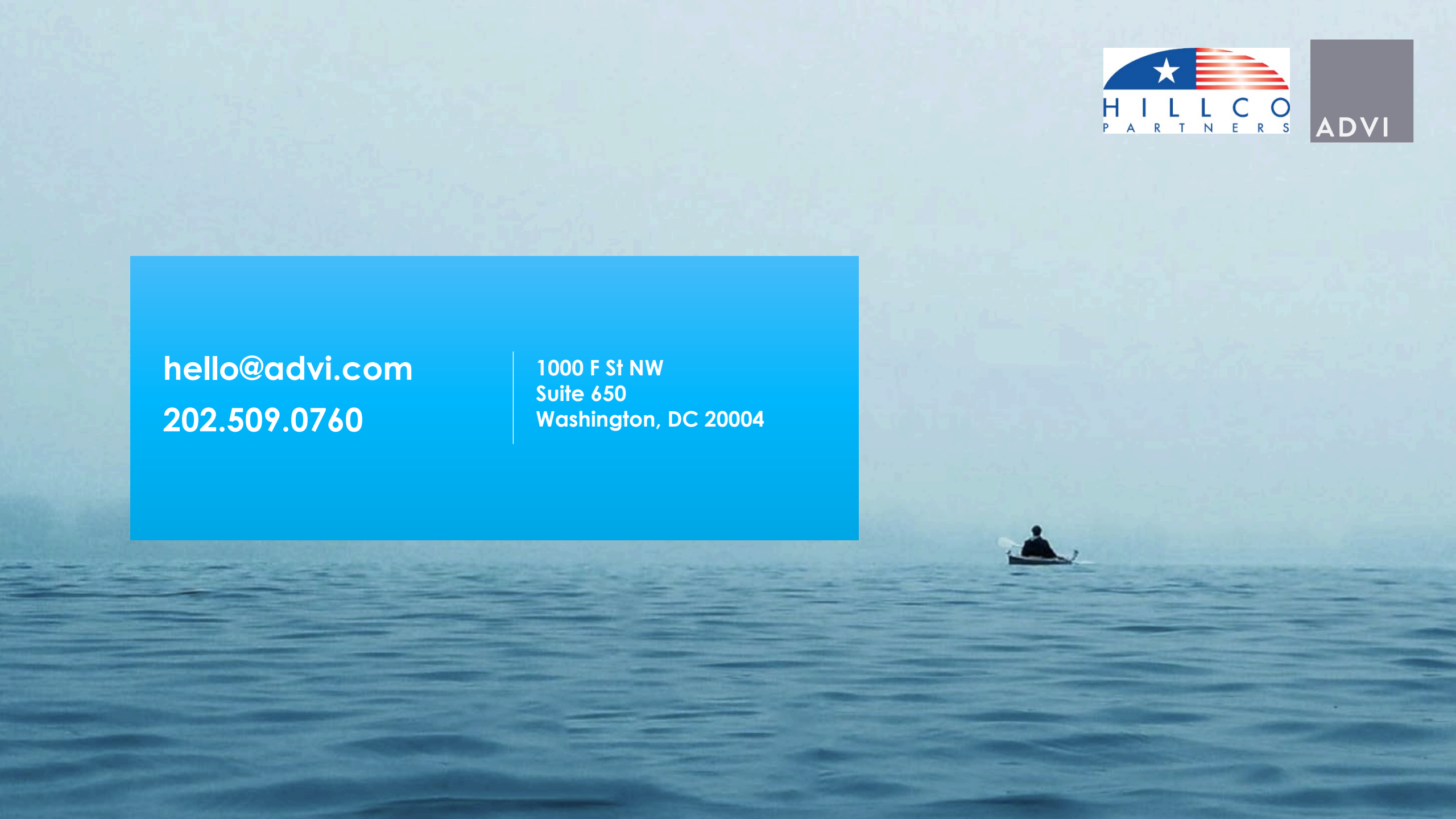
- **HB 2643** - Would have prevented test results for pathology or radiology services that have a reasonable likelihood of finding malignancy or test results **HB 2983** - Woulthat reveal genetic markers from being furnished by electronic means until three days after the test results are finalized.
- **HB 2982** - Would have significantly limited the ability of management services organizations to serve their clients.
- **HB 2983** - Would have helped Texans access healthy foods by creating a pilot program to implement food as medicine programs in Medicaid.
- **HB 4773** - Would have created any willing provider requirements for health plans.
- **SB 1137** - Would have expanded the patient and provider protections passed last session, specifically HB 1919 and HB 1763 to ERISA plans.
- **SB 1581** - Would have established the Texas Health Insurance Mandate Advisory Committee to study and make recommendations related to required health plan benefits.
- **SB 2527** - Would have established additional requirements and prohibitions related to the provision telemedicine, specifically as it relates to online mental health providers, prescription of controlled substances, services for minors, etc.

State Budget Health Care Highlights

- The Texas Legislature made broad investments to increase the healthcare workforce through existing programs:
  - an increase of $6 million for a total of almost $80 million total for the Physician Education Loan Repayment Program
  - An increase of $7 million for a total of $16.5 million for the Family Practice Residency Program
  - An increase of $34 million, for a total of $233.1 million, for Graduate Medical Education slots
  - Increases the Nurse Faculty Loan Repayment Program by $4.1million for a total of $7 million
  - An increase of $27.9 million for the Professional Nursing Shortage Program, for a total of $46.8 million
  - $28 million for the Mental Health Loan Repayment Program
  - $25 million for nursing scholarships
  - $6 million for a Nursing Innovation Grant Program
  - A requirement for the Texas Higher Education Coordinating Board to develop a report on social work workforce and the state's needs

State Budget Health Care Highlights

- The Texas Colorectal Cancer Initiative, a new program developed with the leadership of David Lakey, M.D., with the University of Texas System, was funded with $10 million for the treatment of colorectal cancer for uninsured and underinsured Texas residents at or below 200 percent of the federal poverty level.
- A 6% increase for reimbursement rates for women's health related surgeries
- Includes $447.2 million in All Funds for women's health programs, an increase of $160.1 million over current spending
- $10 million is appropriated to the Department of State Health Services to increase the number of Women’s Preventative Health Mobile Units
- $65 million is appropriated to Texas Tech University Health Sciences Center at El Paso to support the development of a comprehensive oncology center partnership.



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