

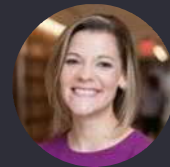


Legislative and regulatory update



Heather Meade

Principal, Washington Council Ernst & Young
Ernst & Young LLP



Laura Dillon

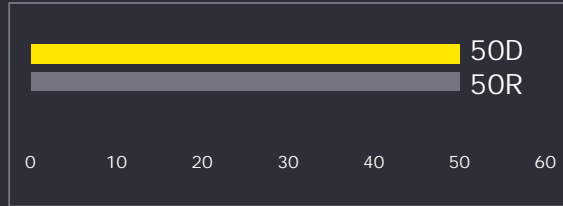
Senior Manager, Washington Council Ernst & Young
Ernst & Young LLP

Election forecast and key issues

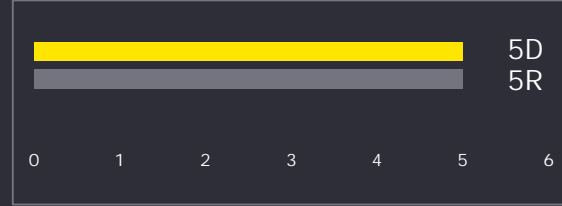


Senate

Current ratio



Toss-up or 'lean' seats



Up for reelection in 2022:

- 21 Republicans
- 14 Democrats

Retiring:

- Roy Blunt (R-MO)
- Richard Burr (R-NC)
- James Inhofe (R-OK)
- Pat Leahy (D-VT)
- Rob Portman (R-OH)
- Richard Shelby (R-AL)
- Pat Toomey (R-PA)

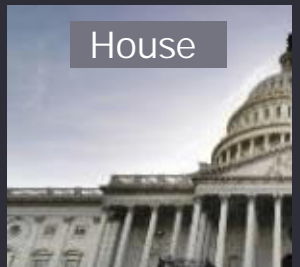
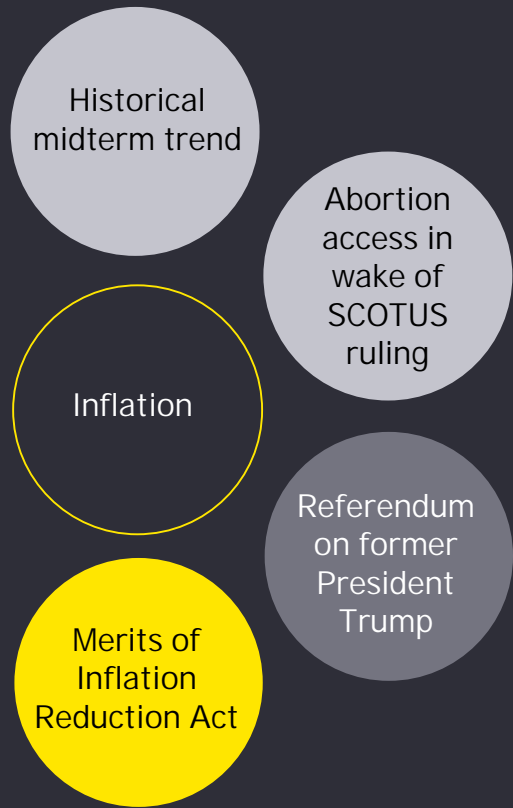
Toss-up D or Lean D:

- Toss up
- Mark Kelly (D-AZ)
 - Raphael Warnock (D-GA)
 - Catherine Cortez Masto (D-NV)
- Lean D
- Maggie Hassan (D-NH)
 - Michael Bennet (D-CO)

Toss-up R or Lean R:

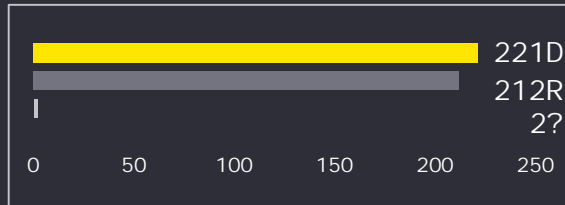
- Lean D
- Penn. open seat (Toomey)
- Toss up
- Ron Johnson (R-WI) Lean R
 - Marco Rubio (R-FL)
 - North Carolina open seat (Burr)
 - Ohio open seat (Portman)

Issues driving the 2022 elections

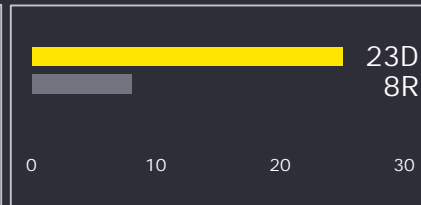


House

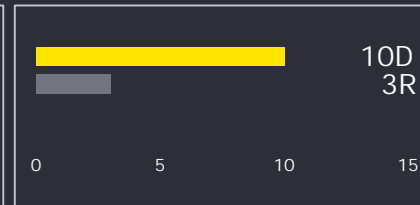
Current ratio



Toss-up seats



Lean to/likely other party



Republicans need a gain of five seats for control (218) presuming they retain control of vacant IN seat

Two vacancies to be decided November 8:

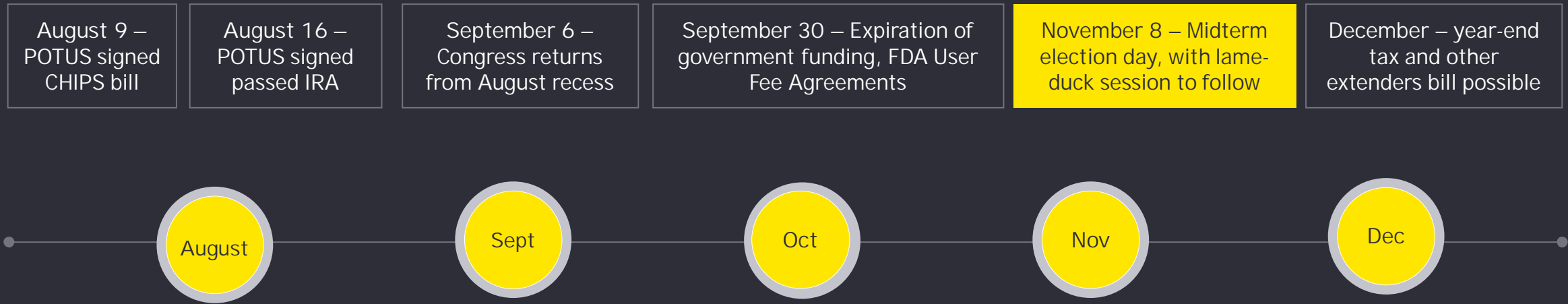
- Rep. Jackie Walorski (R-IN)
- Rep. Charlie Crist (D-FL), who resigned to focus on governor's race

Presidents' party typically loses seats in first midterm:

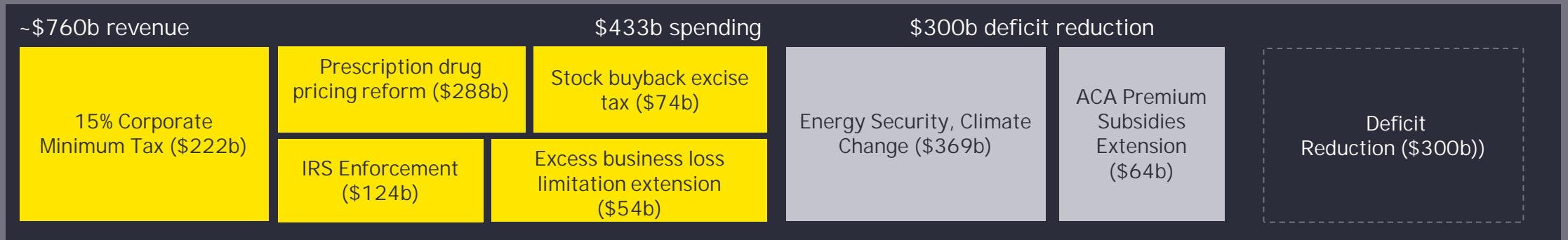
- Trump lost 40 House seats and gained 2 Senate seats in 2018.
- Obama lost 63 House seats and 6 Senate seats in 2010.
- Bush gained 8 House seats and 2 Senate seats in 2002.
- Clinton lost 54 House seats and 8 Senate seats in 1994.

Source: Cook Political Report

Congressional timeline



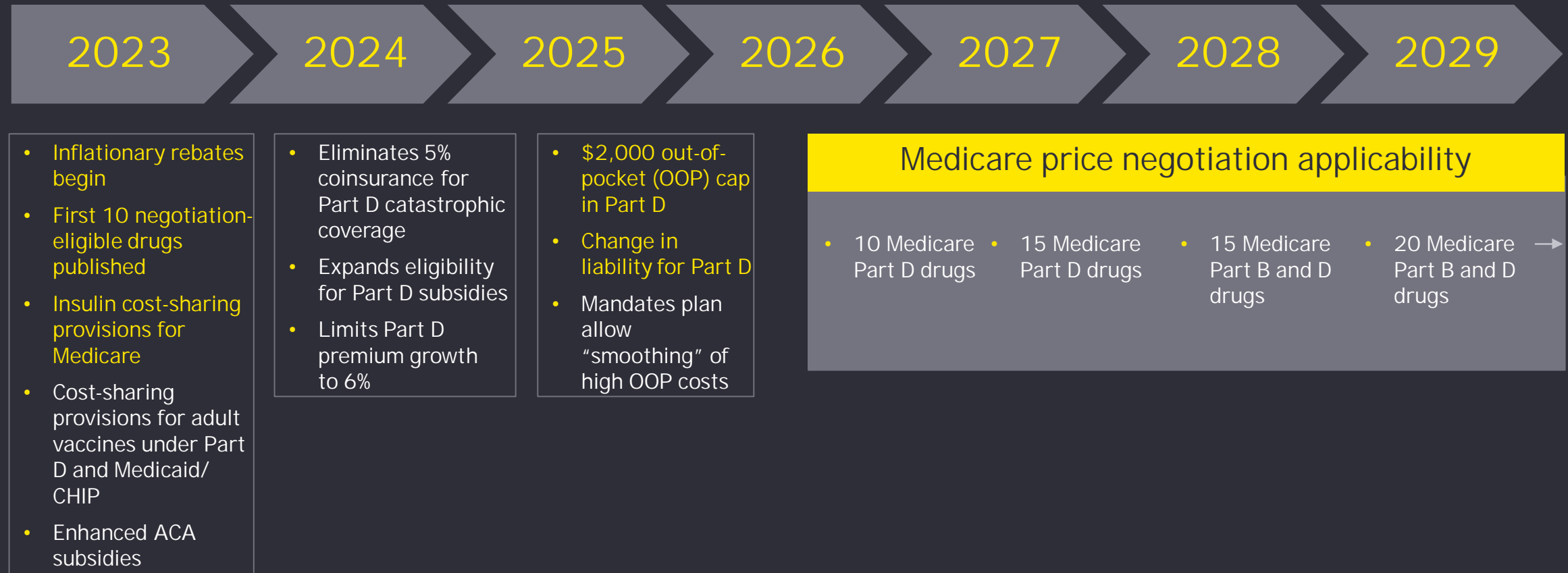
Inflation Reduction Act of 2022



Inflation Reduction Act of 2022

Health	<ul style="list-style-type: none">• Prescription drug provisions: establishes a Drug Price Negotiation program across Medicare Part B and D, prescription drug inflation rebates, a redesign of the Part D benefit, caps out-of-pocket insulin costs for Medicare beneficiaries, and other coverage provisions• ACA subsidies expansion: extends for three years the enhanced ACA subsidies established in the American Rescue Plan Act (ARPA) for three years – through 2025.
Tax	<ul style="list-style-type: none">• Corporate alternative minimum tax (AMT): 15% minimum tax on adjusted financial statement income for corporations with profits in excess of \$1b<ul style="list-style-type: none">• Corporations eligible to claim NOLs and tax credits against AMT and eligible to claim a tax credit against the regular corporate tax for AMT paid in prior years, to extent the regular tax liability in any year exceeds 15% of the corporation's adjusted financial statement income• MACRS depreciation for tangible assets, plus amortization deductions for qualified wireless spectrum, reduces adjusted financial statement income for purposes of computing the tax• 1% stock buyback excise tax : essentially same as House BBBA, but effective after 2022• IRS enforcement: investing \$80b over the next 10 years for enforcement, compliance
Climate	<ul style="list-style-type: none">• Clean energy tax credits: extension of section 45 production tax credit for electricity from renewable resources, section 48 investment tax credit, biodiesel and alternative fuels credits extended through 2024; then transition to technology-neutral credits<ul style="list-style-type: none">• Extensions of 45Q carbon oxide sequestration credit, 48C advanced energy property credit, credits for energy-efficient homes• New credits for nuclear power, hydrogen, sustainable aviation fuel• EV credits for new, used and commercial vehicles with income and MSRP limitations• More than \$20b to support climate-smart agriculture practices• \$27b clean energy technology accelerator• \$6b for a new Advanced Industrial Facilities Deployment Program to reduce emissions

Implementation of the key health care provisions over the next seven years



Source: Inflation Reduction Act; Kaiser Family Foundation.

Medicare drug price negotiation

Overview

Medicare will negotiate maximum fair prices (MFPs) with manufacturers of certain “high-spend” single-source prescription drugs beginning with Part D drugs and then expanding into Part B drugs.

Scope	Negotiation framework
<p>10 → 20 drugs among highest Medicare spend drugs, approved by FDA for at least:</p> <ul style="list-style-type: none"> • >9 years* for small-molecules • >13 years* for biologics 	<p>Maximum fair price defined as the lowest of the Part D enrollment-weighted negotiated price, the Part B average sales price, of a % of the drug’s NFAMP¹:</p> <ul style="list-style-type: none"> • ≤75% NFAMP for Short Monopoly Tx & Vaccines (<12 years) • ≤65% NFAMP for Extended Monopoly Tx (12–16 years) • ≤40% NFAMP for Long Monopoly Tx (>16 years)

Enforcement

Excise tax of 65%–95% of sales for noncompliance
Or 10x the difference if price above negotiated price

Estimated impact (CBO analysis)

Approximately \$99 billion in savings from 2022–2031
–2 drugs introduced between 2023 and 2032; –5 over next decade; –8 over following decade

Source: Inflation Reduction Act; CBO.

*Products may be selected for negotiation earlier, after 7 and 11 years, respectively.

1. Nonfederal average manufacturer price.

Source: Inflation Reduction Act; CBO.

* The selected drug numbers are cumulative, and drugs that are already selected will not count toward these thresholds in subsequent years. The list of negotiation-eligible drugs comprises the 50 drugs with the highest Part D expenditures (2026 and 2027) and also the 50 drugs with the highest Part B expenditures (2028 and subsequent).

Medicare negotiation: implications for providers

340B program	Part B reimbursement
<ul style="list-style-type: none">• The maximum fair price (MFP) is required to be given to 340B covered entities with respect to maximum price entitled individuals if the 340B ceiling price is higher• Protects from “duplicate discounts” under the program, enabling hospitals to purchase products of the lower of the 340B ceiling price and the MFP.	<ul style="list-style-type: none">• The maximum price must be provided to hospitals, physicians, and other providers of services, when eligible individuals are administered the drug• Part B reimbursement for selected drugs will be maximum fair price (MFP) plus 6% as opposed to 106% of the average sales price (ASP).• The MFP will likely be lower than the ASP, so the dollar value of add-on payments will likely decline.

Inflationary rebates

Overview

IRA establishes mandatory rebates for Medicare Part B and D drugs with prices increasing faster than the rate of inflation (CPI-U)

Scope

Inclusions:

- Single-source drugs and biologicals
- Covered under Medicare Part B or Part D
- Exclusions:
 - Certain vaccines and low-cost drugs

Payment framework

- The inflationary rebate amount is the difference in price increases above the cost of inflation
- Inflation defined as CPI-U
- Applicable to Medicare Units

Enforcement

Should a manufacturer not pay the rebate, manufacturers will be subject to a civil monetary penalty equal to or at least 125% of the rebate.

Estimated impact (CBO analysis)

Approximately \$100 billion in savings from 2022-2031 – approximately \$62 billion from discouraging drug companies from raising prices and approximately \$38 billion in revenue generated from rebates paid

Source: Inflation Reduction Act; CBO.

Part D redesign: changes to the catastrophic phase of the benefit

Overview

The Act institutes a cap on beneficiary spend and further shifts costs in the catastrophic coverage period from Medicare beneficiaries and Medicare to plans and manufacturers

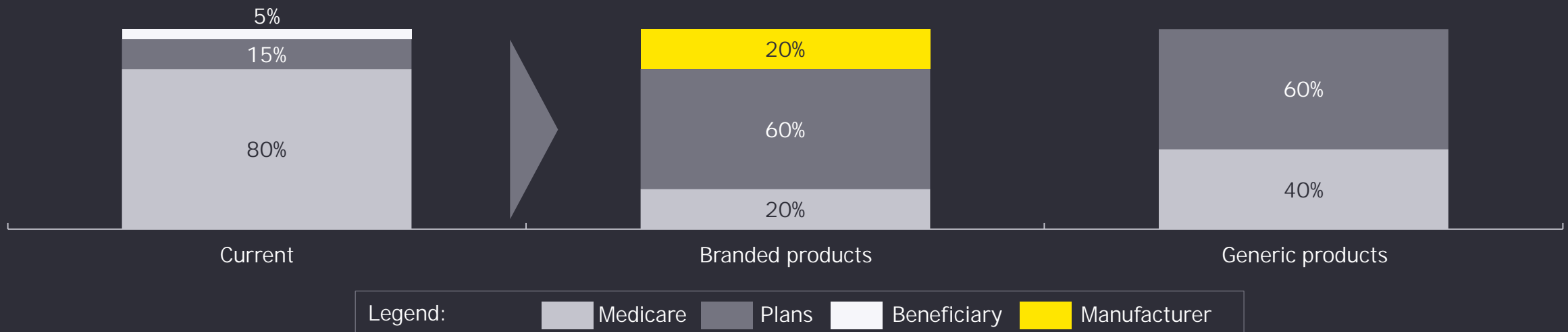
Current law

No out-of-pocket cap

Inflation Reduction Act*

- \$2,000 out-of-pocket cap

Share of costs in catastrophic coverage period



*In the initial coverage phase, the liability levels are as follows: Beneficiary: 25%; Plan: 65%; Manufacturer: 10% brands/biologics. Manufacturers are also not subject to liability for negotiated drugs, and Medicare liability is phased in for certain low-spend and small manufacturers.

Source: Inflation Reduction Act.

Other Part D policies and coverage for vaccines

Insulin provisions

- Beginning in 2023, limits copayments to \$35 per month per prescription for covered insulin products in Medicare Part D plans and for insulin furnished through durable medical equipment under Medicare Part B, with no deductible
- For 2026 and beyond, limits monthly Part D copayments for insulin to the lesser of:
 - \$35
 - 25% of the maximum fair price (in cases where the insulin product has been selected for negotiation)
 - 25% of the negotiated price in Part D plans

Low-income subsidies

- Expands eligibility for full LIS benefits to individuals with incomes between 135% and 150% of poverty and higher resources (at or below the limits for partial LIS benefits), and eliminates the partial LIS benefit

Vaccine coverage

- Medicare Part D: Eliminates cost sharing for adult vaccines covered under Medicare Part D that are recommended by the Advisory Committee on Immunization Practices (ACIP), such as for shingles.
- Medicaid/CHIP: Requires state Medicaid and CHIP programs to cover all approved vaccines recommended by ACIP and vaccine administration, without cost sharing

Three-year extension of ARPA subsidy expansions on ACA marketplaces

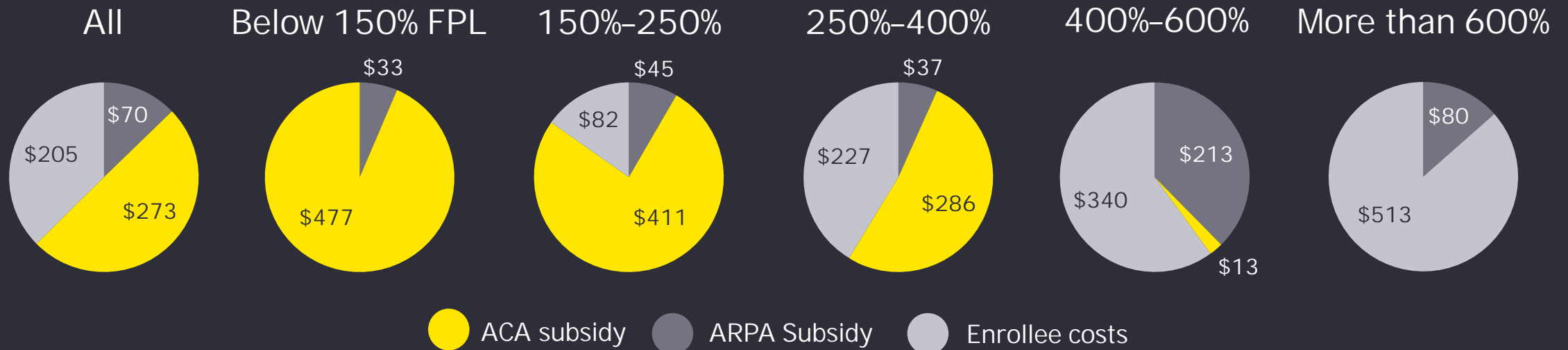
American Rescue Plan Act (ARPA)

- ARPA expanded subsidies available in the ACA's health insurance marketplaces for two years – 2021 and 2022
- The changes included removing a subsidy "cliff" at 400% of the federal poverty level (FPL) and increasing subsidies for those making between 100%–400% of FPL

Inflation Reduction Act (IRA)

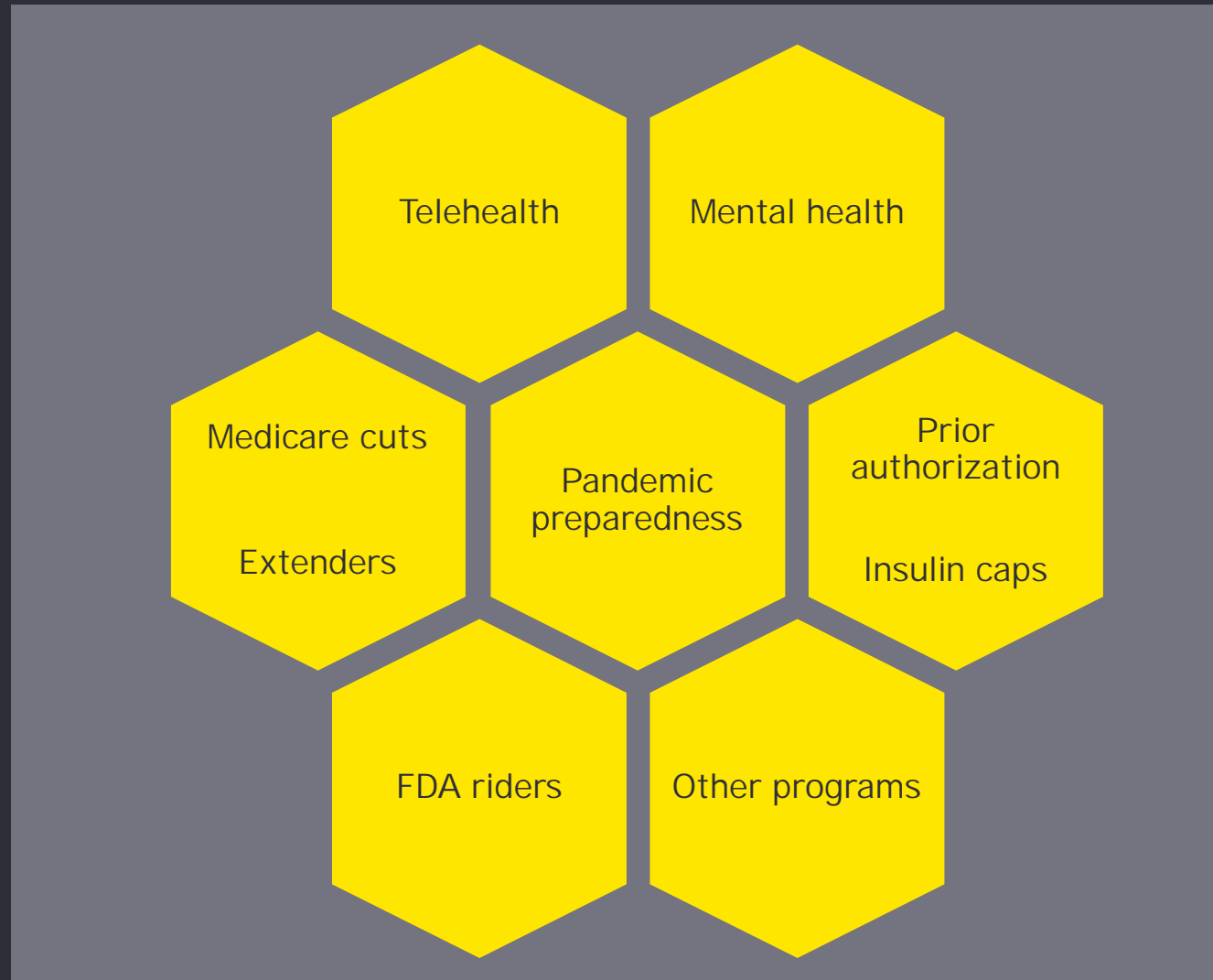
- The IRA expands the enhanced ARPA subsidies for an additional three years – through 2025
- CBO estimates the expansion will cost \$64 billion
- The bill does not close the Medicaid gap, which impacts people who make less than 100% FPL and live in states that have not expanded Medicaid.

How enhanced subsidies affect marketplace shoppers, on average



Source: Inflation Reduction Act; CBO; Kaiser Family foundation.

Congressional health care “to-do list” for remainder of 2022



Congressional focus on mental health, which has been highlighted throughout the pandemic

Several committees have jurisdiction over the issue and have held markups or plan to release legislation in the coming weeks.

Senate Finance Committee

Senate Finance Committee Chair Ron Wyden (D-OR) plans to draft bipartisan legislation aimed at addressing the shortfalls in America's mental health care system focused on five areas of note:

- Strengthening the workforce
- Increasing integration, coordination and access to care
- Helping to ensure mental health parity
- Furthering the use of telehealth
- Improving access for children and young people

On June 15, the Committee unveiled the first of the five expected bills: a discussion draft focusing on children's mental health.

House Energy & Commerce

On May 18, the Committee advanced the Restoring Hope for Mental Health and Well-Being Act of 2022, which reauthorizes 30+ federal mental health and substance use programs.

- On June 22, the bill passed the House.

House Education & Labor

On May 18, the Committee advanced three measures out of committee:

- The Mental Health Matters Act to help ensure employer-sponsored health plans offer mental health and substance use disorder services and support school-based programs
- Enhancing Mental Health and Suicide Prevention Through Campus Planning Act
- Campus Prevention and Recovery Services for Students Act of 2022

House Ways & Means

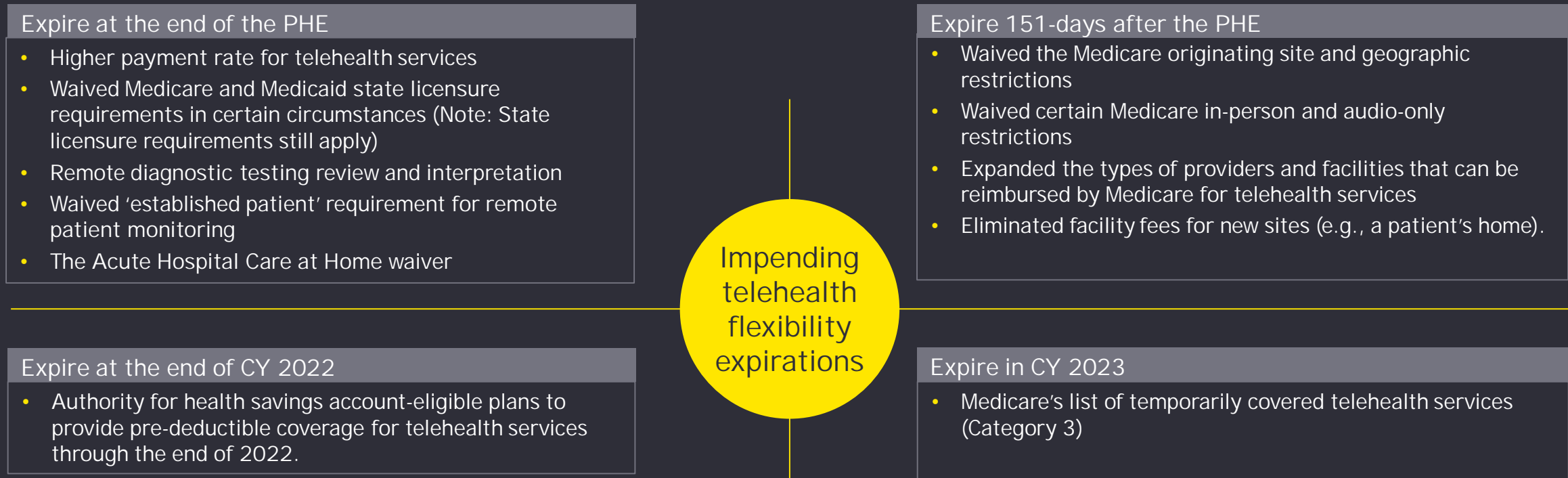
On September 20, the Committee advanced five mental health packages including:

- Improvements to Medicare Inpatient and Outpatient Mental Health Services
- Improvements to the Medicare Program Related to Physician Services and Education
- Requiring Coverage of Forensic Medical Exams with No Cost Sharing
- Improved Information in Provider Directories, Plan Definitions, and Crisis Services for Private Insurance Plans
- Improved Information for Network Coverage and Plan Documents in Private Insurance Plans

Senate HELP Committee

The Senate HELP Committee also has jurisdiction over the reauthorization of federal programs to support mental health and substance use disorders and will need to take up legislation before programs expire.

Congress also focused on expansion of pandemic-era telehealth flexibilities



Flexibilities with unknown end dates

CY in which PHE ends	Direct supervision. CMS allowed direct supervision to be provided using real-time audio and video technology, instead of in-person.
TBD	Certain telehealth flexibilities implemented via guidance and enforcement discretion can be rolled back at any point, though many are likely to be rolled back with the PHE. These include allowing providers to waive or reduce beneficiary cost-sharing obligations for telehealth and allowing approved providers to remotely prescribe controlled substances.

Cuts to Medicare and physician fee schedule in effect and pending Congressional action

Across-the-board Medicare rate decreases

	Public Health Emergency	April 1–June 30, 2022	After June 30, 2022	January 2023
4% Medicare "PAYGO" cuts	Not in effect; debt on the PAYGO scorecard pushed onto 2023 balance sheet, effectively deferring these automatic cuts until 2023.			Barring Congressional action, PAYGO cuts will take effect, which has never been allowed.
2% Medicare sequestration	Congress suspended cuts through March 2022	Smaller 1% cut to Medicare takes effect	Full 2% cut to Medicare takes effect through FY 2031 (in effect)	

Potential Medicare physician fee schedule (MPFS) rate decrease

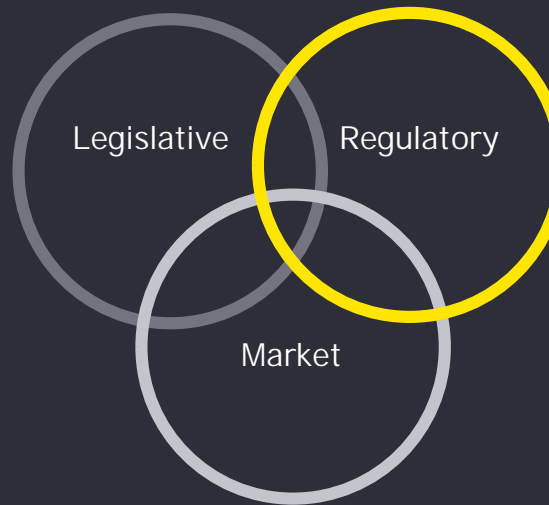
	2021	2022	2023
Increase to physician fee schedule	One time 3.75% pandemic-related boost to the fee schedule conversion through 2021	Smaller bump of 3% for calendar year 2022	Expected end to fee schedule bumps, barring additional Congressional action

Proposed cuts to MPFS for 2023

- Proposed 4.42% reduction of the conversion factor in MPFS rule, accounting for the expiration of the 3% increase in physician payments from 2022.
- Congressional proposal to increase conversion factor by 4.42% for 2023.

Focus on health equity in Washington across the board

The equity agenda



Legislative

- Equity is a key consideration in nearly every health bill
- For example, the user fee bills include clinical trial diversity efforts, more engagement of diverse patient populations and endpoints, and a focus on rare diseases
- Key consideration in discussion around mental health, telehealth, pandemic preparedness, and more

Regulatory

- Equity is a key pillar of CMS strategy and CMS Innovation Center payment models moving forward
- New hospital payment rules highlight enhanced focus on equity, including new reporting requirements, metrics, and data collection
- Administrative efforts as well around hunger, climate change, and more:
 - In September, the White House hosted the first Conference on Hunger, Nutrition and Health
 - HHS has called on health care stakeholders to sign on to a climate pledge to reduce emissions

Market focus

- Addressing health equity has become an imperative for the health sector – for patients, clients, and employees
- Addressing health equity and/or social determinants of health is top of mind for employers
- Increased access to behavioral health care, virtual health care, and voluntary benefits to address individual employee needs are priorities

HHS spring proposed payment rules contain concerning rate updates, highlight a commitment to health equity and enhanced data collection

Key proposals

Hospital inpatient rule (final)

- Update to payment rates by 4.3% – higher than the proposed 3.2% rate increase due to higher market basket update
- Three new health equity measures and three new measures aimed at improving maternal health along with a new “birthing-friendly” hospital designation
- Seeks comment on ways to better incorporate health equity data into hospital quality programs and understand how hospitals think about social determinants of health and climate change
- Continues to suppress certain measures due to COVID-19 and continue some COVID-19 reporting
- 5% cap on wage index decrease

Physician fee schedule (proposed)

- 4.42% reduction of the conversion factor, accounting for the expiration of the 3% increase in physician payments from 2022
- Changes to ACO benchmarks and metrics aimed at sustaining long-term participation and rewarding provision of care for underserved populations; payment flexibilities for certain low-revenue ACOs to address patients’ social needs
- Delay to the split (or shared) Evaluation and Management (E/M) visits policy
- Proposals aimed at expanding access to behavioral health services, dental care, chronic pain management, and colorectal cancer screening.

Hospital outpatient/ASC rule (proposed)

- Update to payment rates by 2.7% for hospitals and ASCs
- Planned reversal of 340B payment cuts and budget neutral adjustments, not reflected in proposed rule due to timing
- Enhanced payments for Rural Emergency Hospitals (REH), a new provider type beginning in 2023
- Continues pandemic-era flexibility allowing for clinical staff of hospital to provide behavioral telehealth
- Exempts Rural Sole Community Hospitals from site-neutral clinic visit payments policy
- Adds biweekly lump sum payment for domestically produced N95s
- RFI on health care competition

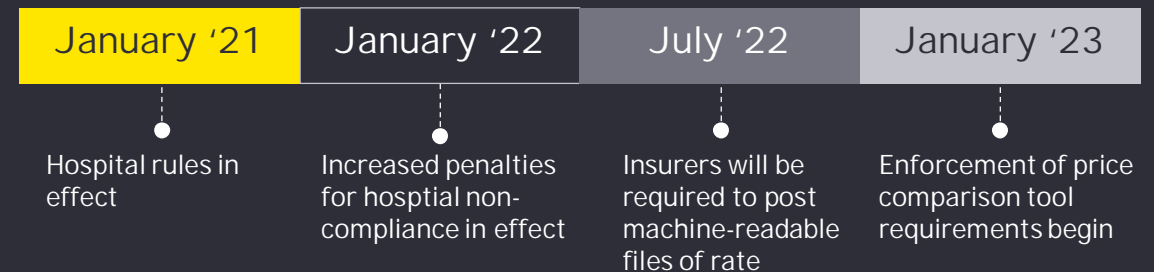
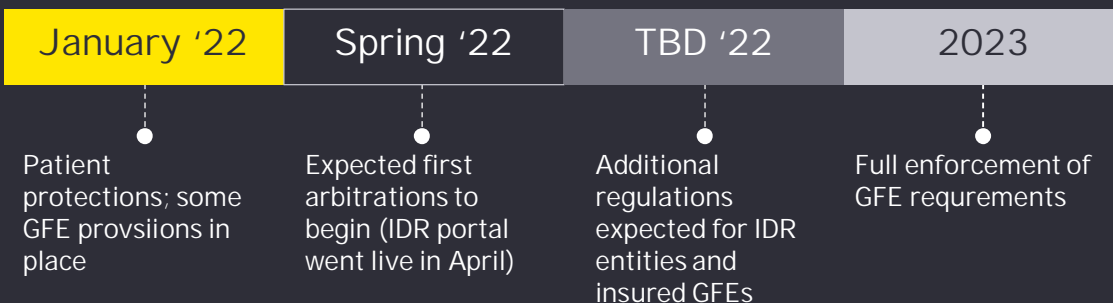
Surprise billing and price transparency rules: implementation timeline and updates

Surprise Billing Rules

- Surprise billing protections: Provisions protecting patients from “surprise bills” in emergency situations and certain non-emergency services at in-network facilities in place January 1, 2022.
- IDR process and legal efforts: In February, a federal court struck down part of the interim final rule that directed arbiters to prioritize the median in-network rate in payment disputes.
 - In April, the Biden administration issued guidance instructing arbiters to consider other information in tandem, such as training and quality of provider(s).
 - The IDR portal went live in April.
- Good faith estimates (GFE): GFE provisions for self-pay patients took effect January 1, 2022, however certain requirements will not be fully enforced until January 1, 2023. Additional rulemaking is expected for insured patients in the coming months.

Price Transparency Rules

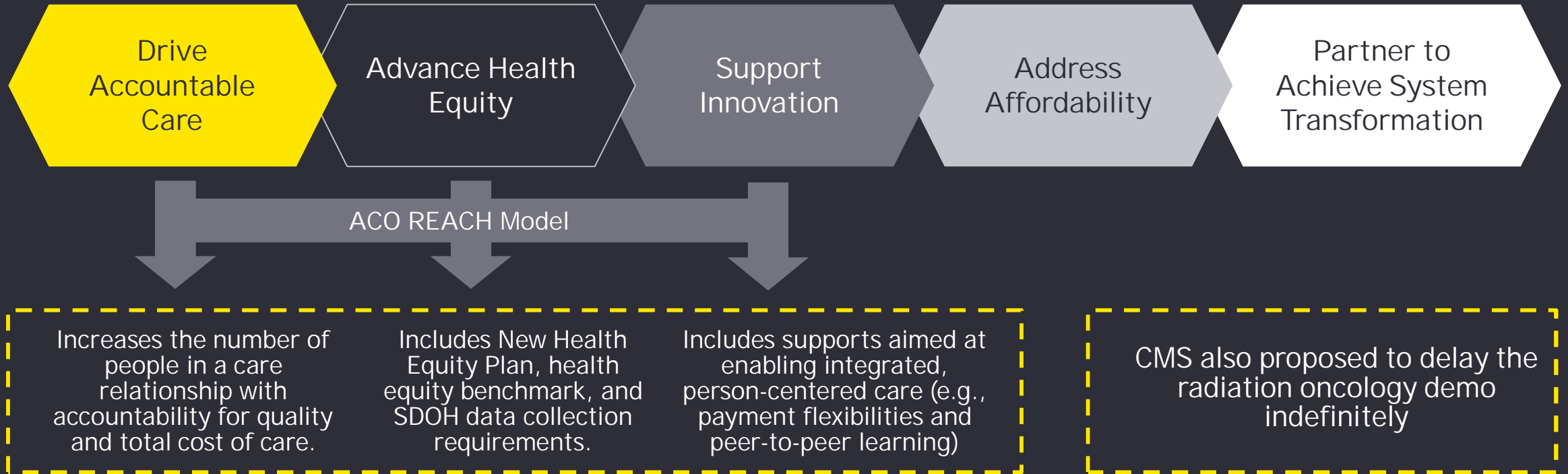
- Hospital transparency rules: Despite legal challenges, the Hospital Price transparency rules went into effect January 1, 2021. According to reports, ~15% of hospitals are fully compliant.
 - The administration ramped up potential penalties from a max of \$300/day to a max \$5,500/day.
 - HHS has issued >350 warning notices, >150 letters for a corrective action plan, and fined two hospitals for violating price transparency rules.
- Insurer transparency rules: Began rolling out July 1, 2022.
 - Posting of machine-readable in-network rates and out-of-network amounts and billed charges will be enforced July 2022, however price comparison tool and other requirements are delayed until 2023.
 - GFE and advanced notice of benefits requirements on hold pending future rulemaking.



CMMI strategy refresh and new ACO REACH Model

CMMI Strategy Refresh: Vision & Strategic Objectives

A health system that achieves equitable outcomes through high-quality, affordable, person-centered care



Source: CMS/CMMI Webinar: "ACO Realizing Equity, Access, and Community Health (ACO REACH) Model Overview Webinar."

Update on the 340B program

Federal reimbursement action

- On June 15, the Supreme Court struck down a 2018 HHS rule that cut outpatient drug reimbursement rates for 340B Program-participating hospitals by nearly 30%.
- The Court unanimously ruled that CMS did not have the authority to enact the cuts because it did not first complete a survey of hospitals' acquisition costs. The Court remanded the case back to the lower courts.
- CMS in its Proposed Outpatient Payment rule noted that it did not have time to make changes to payment following the ruling but that it intends to restore higher payment rates in the final rule.
- On September 28, a District Court judge ruled HHS must immediately halt 340B cuts for the remainder of 2022.

Contract pharmacy restrictions

- Over a dozen drug manufacturers have adopted or announced policies restricting access to 340B drugs at contract pharmacies.
- Court challenges on the topic have issued conflicting rulings and litigation on the matter is ongoing. The Biden administration maintains drug manufactures are violating 340B statute by restricting covered entities access to 340B discounts for drugs dispensed through 340B contract pharmacies, issued guidance and sent letters to manufacturers noting their position.
- HHS' Office of Inspector General opened an investigation into some drug companies' 340B policies to see if they violate federal law. The Biden administration has alerted drugmakers that they are violating federal law by restricting safety net providers' access to products under the program.

Other 340b action

- The Biden administration is working on a proposed rule to create a new 340B dispute resolution process and is considering additional oversight.
- Additional scrutiny of 340B entities is expected to increase with a Republican majority in the Senate and/or House, as many Republicans believe the program has outgrown its original intended scope and intend to help ensure funds linked to community benefit.

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