



# 2022 Midterm Elections Preview OCTOBER 17, 2022

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# 2022 Election Forecast

Congressional Leadership Implications

Voter Priorities Heading into Midterm Elections

2023 Policy Outlook



# 2022 Election Forecast



# White House

President Joe Biden

42.% approval rating, as of Oct. 19, 2022

# Congress

Split Senate 50-50 (+1D from VP)

Democratic House majority 221-212

# Supreme Court

6 Republican appointees

3 Democratic appointees



# White House

President Joe Biden

# Congress

Democrats slightly favored to win Senate

Republicans slightly favored to win House

# Supreme Court

6 Republican appointees

3 Democratic appointees

https://projects.fivethirtyeight.com/2022-election-forecast/



# Senate

- The Senate is currently 50-50, with Vice President Harris as the tiebreaker. Fourteen seats held by Democrats and 21 seats held by Republicans are up for election in November.
- Six of these seats are open due to retiring Senators (NC, PA, AL, OH, VT, and MO).

# House

- Democrats currently have a 9-vote majority in the House (221-212 with 2 vacancies). All House seats are up for re-election in November.
- Democrats have 36 open seats, and Republicans have 28.

# Road to Congressional Majority



	Senate	House
Democrats	50	221 (1 vacancy)
Republicans	50	212 (1 vacancy)

Democrats cannot afford to net a single loss in order to keep control of the Senate.

Republicans need to gain 6 seats to win the majority in the House.



# Senate

- Of the 14 Democratic seats up for reelection, 9 are rated as solid, 3 are "likely Democratic" (AZ, CO, NH) and 2 are rated as "toss-ups" (GA & NV).
- Of the 21 Republican seats, 14 are rated as solid, 4 are "leans Republican" (UT, OH, NC, FL) and 2 are "toss-ups" (WI and PA).<sup>1</sup>

# House

- Prior to the Supreme Court's decision to overturn Roe v. Wade, Republicans were widely expected to take the House. Republicans are still expected to win the majority, but many races have narrowed. Pollsters are taking a much more cautious approach to forecasting these races.
- The majority will likely be decided by roughly 12 "toss up" races (VA-2, AZ-2, AK, NY-19, PA-7, CA-27, TX-15, IA-3, OR-5, CA-22, KS-3, and NM-2).<sup>2</sup>
- 1. The Cook Political Report with Amy Walter (https://www.cookpolitical.com/senate-charts)
- 2. Five Thirty Eight (https://projects.fivethirtyeight.com/2022-election-forecast/house/?cid=rrpromo)

# Top Health-Related Issues on the Campaign Trail



#### **Democrats**

While Republicans are going to be focusing mostly on inflation and the economy, Democrats will include a number of health-related issues including:

- Access to abortions;
- COVID-19: though not at the top of people's minds, it still is an issue for many Democrats;
- Workforce shortage;
- Telehealth waiver extension:
- Extensions of the Affordable Care Act that were included in IRA
- Drug pricing reforms, also included in IRA;
- · Mental health policy; and,
- Health Equity

#### Republicans

Republicans are focusing on inflation and the economy. However, there may be some discussion around:

- Telehealth waiver extension;
- Workforce shortages;
- · Vaccination mandates; and,
- Mental health policy



# Congressional Leadership Implications

## Possible Leadership Changes



#### Republicans

HOUSE: Current Republican House Minority Leader, Kevin McCarthy, is expected to keep his position, particularly if Republicans take control of the House. The race for leader, however, may not be without some challenge from far-right members of the party.

**SENATE:** The only expected change in the Senate Republican leadership is for the Chairman of the Republican Policy Committee. Current Chair Roy Blunt (R-MO) is retiring.

#### **Democrats**

**HOUSE:** In 2018, Speaker of the House, Nancy Pelosi, agreed to only serve 4 years in the position, however, she may elect to try and stay on as leader of the Democratic party, particularly if the Democrats manage to hold on to the House. If she agrees to cede the position, some of the top options to replace her are:

- Steny Hoyer, currently the Majority Leader and next in line;
- Jim Clyburn, currently the Majority whip and 2<sup>nd</sup> in line;
- Hakeem Jeffries- House Democratic Caucus Chair;
- Pramila Jayapal- leader of the Progressive Caucus;
- Katherine Clark- Assistant House speaker

**SENATE:** There are no expected changes to Senate Democratic leadership.

# Possible Leadership Changes of Key Senate Committees



#### **Appropriations**

- **Democrats:** The top Democrat on the Appropriations Committee, **Sen. Pat Leahy (D-VT)** is retiring. Next in line to lead the Committee for the Democrats is **Sen. Patty Murray (D-WA)**. Sen. Murray is expected to keep her position as Chair of the Labor-HHS Subcommittee, even as she takes the full Committee chair.
- Republicans: The Top Republican on the spending Committee, Sen. Richard Shelby (R-AL) is also retiring. Next in line to lead the Committee for the Republicans is Sen. Susan Collins (R-ME). Additionally, Sen. Roy Blunt (R-MO), who is the top Republican on the Labor-HHS Subcommittee is also retiring. Next in line is Sen. Lindsay Graham (R-SC), who would have to give up control of the State-Foreign Ops Subcommittee.

#### Health, Education, Labor and Pensions (HELP):

- Democrats: If Sen. Murray becomes chair of the Appropriations Committee, then Sen. Bernie Sanders (I-VT) is next in line to lead HELP. However, he would likely have to decide between leading the Budget or HELP Committee. If Sen. Sanders passes, Sen. Bob Casey (D-PA) is next in line.
- Republicans: The current Republican lead on HELP, Sen. Richard Burr (R-NC) is retiring this Congress. The next Republican in line to take over the Committee is Sen. Rand Paul (R-KY). This could be a difficult dynamic if Rand Paul and Bernie Sanders are at the helm.

# Possible Leadership Changes of Key House Committees



#### Ways and Means Committee

• Rep. Richard Neal (D-MA) is expected to stay at the helm of the Ways and Means Committee for the Democrats, but the top Republican position is wide open. Current Ranking Member, Rep. Kevin Brady (R-TX) is retiring. The three members vying for the position include: Rep. Vern Buchanan (R-FL); Rep Jason Smith (R-MO); and Rep. Adrian Smith (R-KS). Rep. Buchanan and Rep. Smith are the top two candidates for the position. Though Rep. Buchanan is next in line, Rep. Smith has been aggressively working the Steering Committee for the job.

#### **Budget Committee**

- Current Chairman of the Budget Committee, **Rep. John Yarmouth (D-KY)** is retiring this Congress. Next in line for the position is **Rep. Hakeem Jeffries (D-NY)**. If he happens to rise to Democratic Leader, **Rep. Brian Higgins (D-NY)** is next in line.
- Current Republican Chair, Rep. Jason Smith (R-MO) is leaving the Chairmanship to run for Chair of the Ways and Means Committee. Rep. Lloyd Smucker (R-PA) and Rep. Buddy Carter (R-GA) are running for the position.

#### Oversight and Reform Committee

Congresswoman Carolyn Maloney (D-NY), Chair of the House Oversight and Government Reform
Committee, recently lost her primary bid to Rep. Jerrold Nadler in the newly drawn 12<sup>th</sup> district. Next in
line to take over the Committee for the Democrats is D.C. Representative Eleanor Holmes Norton. This is
particularly important if the Republicans take the House, the Oversight and Government Reform
Committee, led by Rep. James Comer (R-KY) is expected to be very active investigating the Biden
Administration on a host of issues.



Voter Priorities Heading into Midterm Elections

# **Top Voter Priorities**

Economy, abortion and reproductive rights, and immigration issues



#### Figure 4

# The Economy Is The Key Issue Voters Want To Hear Candidates Discuss, Followed by Abortion and Immigration

Thinking about candidates running for elected office this November, what one issue would you most like to hear candidates talk about? (open-end)

		Party ID		Race/Ethnicity			
	Total voters	Dem	Ind	Rep	Black	Hispanic	White
Economic issues	35%	23%	33%	52%	26%	30%	39%
Abortion/Reproductive Rights/Roe v. Wade	15%	28%	14%	5%	19%	15%	15%
Immigration issues	9%	2%	10%	18%	1%	11%	10%

NOTE: Among registered voters. Top three responses among total voters shown. See topline for full question wording, SOURCE: KFF Health Tracking Poll (September 15-26, 2022)



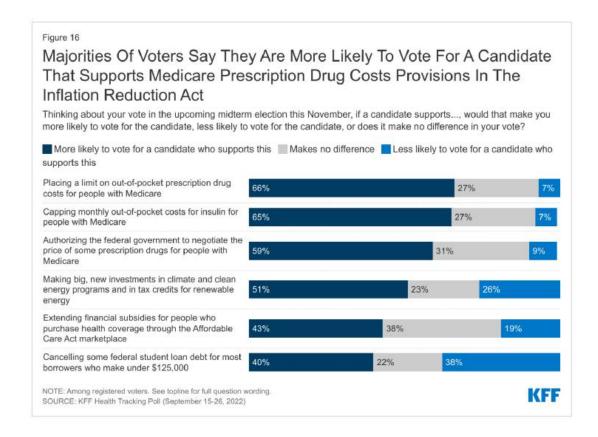
- The economy is a top issue across party lines, especially for Republicans (52%) and independents (33%).
- Democratic voters are more divided on what they consider to be their top issue, with 23% of Democratic voters most concerned about the economy and 28% of Democratic voters most concerned about abortion and reproductive rights.
- Abortion is a top issue for 5% of Republican voters.
- The U.S. Supreme Court overturning *Roe v. Wade,* has motivated half of voters to vote in the midterm election. Motivated voters are about twice as likely to say they plan on voting for candidates who want to protect access to abortion (58%) than for candidates who want to limit abortion access (27%).
- Immigration is the second most important issue motivating Republicans to vote at 18%, compared to 10% of independent and 2% of Democrat voters.

https://www.kff.org/report-section/kff-health-tracking-poll-october-2022-the-issues-motivating-voters-one-month-before-the-midterm-elections-findings/

# Impact of Democrats' Inflation Reduction Act on Midterm Elections

Voters are generally not aware of key health provisions in IRA.





Health care costs, including prescription drug costs, is a key issue for 55% of total voters in the midterm elections (63% for Democrats and 46% for Republicans). Interestingly, most adults are unaware of the following key health provisions from the IRA:

- 66% are unaware that it extends financial subsidies for people who purchase health coverage through the Affordable Care Act marketplace;
- 63% are unaware that it places a limit on out-of-pocket prescription drug costs for people with Medicare;
- 60% are unaware that it caps monthly out-of-pocket costs for insulin; and
- 55% are unaware that it authorizes the federal government to negotiate the price of some prescription drugs for people with Medicare.

Most voters ages 65 and older, who are more likely to know about the IRA health provisions, say they are more likely to vote for a candidate who supports the Medicare provisions in the IRA. Awareness of the climate provisions in the IRA is higher among adults, 42%, compared to some of the health care elements.

https://www.kff.org/report-section/kff-health-tracking-poll-october-2022-the-issues-motivating-voters-one-month-before-the-midterm-elections-findings/



2023 Policy Outlook

# Introduction: Policymaking Windows for 2023

Opportunities for legislation to move forward



# Legislative dynamics following the passage of the Inflation Reduction Act and leading up to the Midterm Elections have muddied the prospects for bipartisan activity on health care for the remainder of 2022

• Both parties appear less likely to work together following the recent passage of the Inflation Reduction Act via the budget reconciliation process, though the year-end spending package could still feature certain high-priority bipartisan initiatives (e.g., mental health, telehealth, etc.).

# The new Congress next year may move forward on health care legislation, however, as upcoming expirations and legislative deadlines may prompt new activity

- **Dec. 16, 2022:** Expiration of continuing resolution for FY 2023 appropriations.
- **Dec. 31, 2022:** Expiration of 5 percent incentive payment for physicians to participate in advanced alternative payment models.
- **January 11, 2023:** Potential expiration date for the COVID-19 public health emergency (PHE).
- June 11, 2023: Potential expiration of Medicare telehealth flexibilities if PHE ends on Jan. 11, 2023.
- **Sept. 30, 2023:** Expiration of PAHPA, last reauthorized under Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (<u>P.L. 116-22</u>). Also, the deadline for FY 2024 appropriations and Farm Bill.
- **Dec. 31**, **2023**: Expiration of various Medicare extenders (e.g., Medicare <u>patient IVIG access</u> demonstration project; <u>independence at home</u> medical practice demonstration program).

### **Outline**

Following slides will discuss potential policymaking in each area



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**Behavioral Health** 

Public Health

Advancing Health Equity/Maternal Health/Reproductive Rights

**Medicaid Reform** 

Medicare Reform

**Cost Control** 

Delivery Reform/Primary Care

Coverage/Affordability Improvements

Nutrition

#### Climate and Health

No Congressional direction yet on climate health, though HHS is attempting to take action



# **Policy Landscape**

The Inflation Reduction Act was the largest investment in climate change policies to date and represented a major win for congressional Democrats. However, the IRA did not include any specific programs or provisions for health care. HHS has not taken much regulatory action on climate change but did invite organizations to sign a <u>climate pledge</u> to lower emissions.

# **Legislative Opportunities**

- The newly established HHS Office of Climate Change and Health Equity has yet to receive any funding but could be funded through appropriations
- Members discussed health care infrastructure and climate change in the Ways and Means Committee and agreed on bolstering US energy infrastructure but did not discuss any legislation
  - Democrats also released a <u>report</u> that addresses the impact of climate change on health care and ways that the health care system contributes to climate change
  - Democrats suggested directing NOAA to provide hospitals with hyperlocal sever weather warnings and predictions on the impact of climate change
    - The WH launched the Climate Mapping for Resilience and Adaptation <u>portal</u>

- HHS partnered with the National Academy of medicine on the <u>Action Collaborative on Decarbonizing the US Health</u> <u>Sector</u>, a voluntary collaborative of organizations committed to addressing the industry's contributions to climate change and ways to make it more sustainable and resilient
- The Council on Environmental Quality (CEQ) is <u>expected</u>
  to issue guidance to federal agencies on how to assess the
  greenhouse gas emissions and climate change impact of
  their proposed actions
- The EPA and IRS will begin implementing climate change provisions from the IRA including a lot of investment and tax credits to support clean energy and transportation
- The recently released White House strategic plan on nutrition and health states that it will begin investigating the intersection of climate change, food security, and nutrition.

#### Behavioral Health

Legislation on behavioral health could occur in the next Congress; Administration will support with grantmaking and guidance



#### **Policy Landscape**

Congress appears interested in advancing bipartisan legislation on behavioral health, though the chances of that occurring this Congress continues to decline. Current deliberations may inform lawmaking on behavioral health for the next Congress. The Administration is also executing on its strategy to reform behavioral health.

#### **Legislative Opportunities**

- Bipartisan legislation could be included in a year-end spending package, though Senate Republicans have intimated they are less interested in passing additional behavioral health legislation beyond the Bipartisan Safer Communities Act, especially in the wake of the recent budget reconciliation process.
- Several Congressional Committees are activated on behavioral health reform:
  - Senate Finance has released three discussion drafts for legislation on behavioral health workforce, telehealth, and youth mental health. Two more are expected on parity and behavioral health integration.
  - Senate HELP and the House E&C Committees have worked on packages that would reauthorize funding for various existing mental health programs
  - House W&M advanced bills that aim to improve access to mental health services under Medicare and private health insurance

- The Administration is preparing to support the behavioral health system in the following ways:
  - Grants to support hiring of mental health professionals at schools, the CCBHC demonstration, access to children's mental health services, training for pediatric providers, enhancing the 988 suicide hotline, and more
  - Guidance to state to encourage them to leverage Medicaid's existing "free care" policy
  - Guidance on leveraging the Medicaid Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit
  - Training on ACEs
  - Awarding a new Center of Excellence on Social Media and Mental Wellness
- Expected rulemaking on mental health:
  - Proposed rule to clarify plans' obligations under the Mental Health Parity and Addiction Equity Act
  - Proposed rules that would permanently extend certain COVID-19 flexibilities for opioid treatment via telehealth

#### **Public Health**

Data, infrastructure, community trust, pandemic response



## **Policy Landscape**

Biden's "<u>Funding Request to Meet Critical Needs</u>" includes \$22.4 billion in COVID-19 funding, \$3.9 billion for monkeypox and funding for natural disasters.

### COVID funding is intended for:

- Testing;
- Research and development of next generation vaccines and therapeutics;
- Preparation for future variants; and
- Support for the global COVID-19 response.

Absent funding, there will be challenges replenishing the national stockpile, limited ability to send free home tests + diminished domestic testing capacity more broadly.

Potential but slim chance of inclusion in an end of year package.

Opportunities in 2023 depend upon election outcomes.

Notably, PAHPA expires in late 2023 and is up for reauthorization. Grant opportunities through CDC or ASPE could be shaped to build community trust and maximize the public health impact.

## Public Health (cont.)

Data, infrastructure, community trust, pandemic response



# **Legislative Opportunities**

# Regulatory & Grant Opportunities

## 2022

- Continuing Resolution
- End of Year Package

## 2023

- Pandemic and All-Hazards Preparedness
   Act (PAHPA) Reauthorization
  - Current PAHPA expires in 2023.
- Murray-Burr <u>PREVENT Pandemics Act</u>
  - Could be part of PAHPA
- Public Health Infrastructure Saves Lives Act
  - Funds CDC and health departments

- Data modernization, including implementation of <u>CMS</u> requirements related to public health data sharing
- Grant opportunities may exist within ASPE or CDC
- Investments in trusted messengers are needed to build community trust.

# Advancing Health Equity/Maternal Health/Reproductive Rights

Direction on reproductive rights and health equity depend in part on Midterm elections



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#### **Policy Landscape**

- U.S. Supreme Court overturned Roe v. Wade; currently 9 states ban abortion completely
- Sen. Lindsey Graham <u>introduced</u> federal 15-week abortion ban; currently 4 states have 6-week bans, 1 state has 15-week ban, 31 states have ban after 15 weeks
- FY 2022 omnibus appropriations package included <u>nearly \$1 billion</u> in maternal health priorities

Legislative Opportunities	Regulatory Opportunities
<ul> <li>Prospects for bill to codify constitutional right to abortion hinge on 2022 elections</li> <li>Funding for FY 2023 Title X family planning grants <ul> <li>\$286 million appropriated in FY 2022</li> <li>President requested \$400 million</li> <li>House passed \$500 million</li> <li>Senate Democrats propose \$512 million</li> </ul> </li> </ul>	<ul> <li>CMS NPRM reinstating and strengthening Section 1557 protections (WHG summary)         <ul> <li>Comments due Oct. 3, 2022</li> </ul> </li> <li>CMS RFI on (1) accessing healthcare and related challenges, (2) understanding provider experiences; (3) advancing health equity; and (4) the impact of the COVID-19 public health emergency (PHE) waivers and flexibilities         <ul> <li>Comments due Nov. 4, 2022 (WHG summary)</li> </ul> </li> </ul>
<ul> <li>Post-election Senate vote on House-passed Respect for Marriage Act (<u>H.R. 8404</u>)</li> <li>Not yet scheduled House vote on Jackie Walorski Maternal and Child Home Visiting Reauthorization Act of 2022 (<u>H.R. 8876</u>) W&amp;M Committee</li> </ul>	<ul> <li>CMS NPRM, "Culturally Competent and Person-Centered Requirements to Increase Access to Care and Improve Quality for All" forecasted March 2023         <ul> <li>Would revise CoPs for Medicare and Medicaid</li> </ul> </li> <li>Continued implementation of the EO on reproductive health         <ul> <li>HHS encourages states to pursue section 1115 waivers to expand access to abortion care for women traveling from a state that has restricted or prohibited abortion</li> </ul> </li> </ul>

#### **Medicaid Reform**

Legislative reform to Medicaid remains politically charged



#### **Policy Landscape**

- Despite ARPA incentive for Medicaid expansion, Medicaid expansion is politically charged. Efforts for a Medicaid gap coverage program failed with BBBA.
- Unwinding of Medicaid continuous coverage requirements could begin early November if COVID-19 PHE expires in January 2023.

#### **Legislative Opportunities**

#### Provide 12 months of continuous eligibility for all children in Medicaid/CHIP (currently possible through a SPA, adopted in <u>24 states</u>)

- Give states the option to provide continuous eligibility to adults through a SPA (currently possible through 1115 waiver process but is burdensome and only two states have done this)
- Require all states to extend Medicaid postpartum coverage to 12 months permanently (currently possible through a SPA for five years thanks to ARPA)

#### **Regulatory Opportunities**

- CMS NPRM, "Medicaid Program and CHIP; Mandatory Medicaid and Children's Health Insurance Program (CHIP) Core Set Reporting"
  - Requires states to report standardized children's health quality measures for Medicaid and CHIP, behavioral health measures for adults in Medicaid, and health home quality measures
  - Comments due Oct. 21, 2022 (WHG summary)
- <u>CMS NPRM</u>, "Streamlining the Medicaid, Children's Health Insurance Program, and Basic Health Program Application, Eligibility Determination, Enrollment and Renewal Processes" Remove barriers and facilitate enrollment;
  - Align enrollment and renewal requirements for most individuals in Medicaid;
  - Create beneficiary protections with respect to returned mail;
  - Create timeliness requirements for Medicaid and CHIP redeterminations;
  - Make transitions between programs easier;
  - · Eliminate access barriers for children enrolled in CHIP; and
  - Modernize recordkeeping requirements to ensure that eligibility and enrollment are properly documented.
  - Comments due Nov. 7, 2022 (WHG summary)
- CMS NPRM, "Assuring Access to Medicaid Services" is forecasted for February 2023
  - Would propose changes to support comprehensive access strategy and payment processes

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#### **Medicare Reform**

PHE's End Will Offer Best Chance for Reforms



#### **Policy Landscape**

With a divided Congress anticipated, opportunities to make bold Medicare reforms will be slim. However, the end of the PHE could be the push that is needed to make permanent some of the most popular and impactful COVID-19 Medicare flexibilities such as those related to telehealth or Hospital at Home. Policies with broad public and bipartisan support and those that do not require legislation to implement have the greatest chances of advancing in this environment.

#### **Legislative Opportunities**

- Republicans recently released a plan that highlights their health care priorities after the midterms, they pledge to "lower prices through transparency, choice and competition, invest in lifesaving cures, and improve access to telemedicine."
- Passage of an omnibus spending bill could slip to early 2023 and might offer an opportunity for Medicare reform policies that have bipartisan support
- Lawmakers may intervene to further expand telehealth before the end of the 151 day extension after the PHE expires – if the PHE ends on Jan. 11, telehealth flexibilities would end on June 11
- MedPAC's March and June reports could prompt the introduction of legislation related to the Commission's recommendations. This cycle, the Commission is considering a range of issues, including:
  - Standardizing MA benefits;
  - Reforming the wage index system; and
  - Lowering Part B drug spending.

- Responses to CMS' RFI on the impact of the COVID-19 PHE waivers and flexibilities (due Nov. 4, 2022) could inform further action by the agency in 2023
- OCR expects to finalize a rule in March 2023 that would strengthen individuals' rights to access their own PHI and improve information sharing for care coordination, as well as increase family and caregiver involvement, among other changes
- After a series of listening sessions earlier this year, CMS
  expects to propose a rule in April 2023 that would establish the
  criteria for an expedited coverage pathway to provide Medicare
  beneficiaries with faster access to innovative and beneficial
  technologies
- Certain policies, such as those related to quality and valuebased purchasing, could be addressed through the Medicare annual payment rules as part of the regular rulemaking cycle. Proposed FY rules are generally released in the spring while proposed CY rules are expected in the summer. CMS generally begins working on these rules about 6 months before they are released

#### Cost Control

Looming insolvency could prompt action on physician payment and MA reform



#### **Policy Landscape**

Efforts to control Medicare spending will likely increase in prominence as we continue to approach the insolvency date, now targeted for <u>2028</u>. However, additional legislative action specifically on drug pricing is less likely following IRA. Further action on drug pricing will be carried out by the Administration.

# **Legislative Opportunities**

- Physician Payments: Bipartisan group of 8 House members are seeking feedback on how to improve the Medicare Access and CHIP Reauthorization Act (MACRA), with an ultimate goal of creating stronger incentives that push Medicare towards value-based care (responses due Oct. 31). The same lawmakers introduced legislation to prevent the upcoming 4.42 percent cut to Medicare physician payments that are set to begin on Jan. 1, 2023, which could evolve into more comprehensive legislation to reform MACRA based on the RFI responses.
- Medicare Advantage: Congress has engaged in efforts suggesting it may look into Medicare Advantage-related reform, including an oversight hearing on MA plan practices and an RFI on MA marketing practices. MedPAC is also closely examining issues with MA encounter data. The next Congress could pursue legislation to prevent against overpayments.

- Physician Payments: CMS may continue work on strengthening the MSSP and bringing more physicians into two-sided risk ACOs (per recent proposals in the 2023 Medicare Physician Fee Schedule proposed rule), especially as it learns from current and future accountable care-focused demonstrations.
- Drug Pricing: HHS will implement the Inflation Reduction
  Act drug pricing provisions in the coming years.
  Additionally, President Biden <u>issued</u> an executive order
  that directs HHS to consider testing a new demonstration
  model through CMMI to lower drug costs and promote
  access to innovative drug therapies for Medicare and
  Medicaid beneficiaries (see appendix slides for more
  details).

## Delivery Reform/Primary Care

CMMI will continue to lead on delivery reform efforts, with a focus on health equity and accountable care



#### **Policy Landscape**

Delivery reform is likely to move forward via regulatory action given CMMI's broad waiver authority, though some legislative action is not impossible.

#### **Legislative Opportunities**

- While there has not been major legislative focus on primary care reform, legislation has been introduced this Congress that would support a model of care known as Direct Primary Care (DPC). DPC is a model of care in which patients/consumers pay their physician or practice directly in the form of periodic payments for a defined set of primary care services. The legislation would allow individuals to use their HSAs for DPC payments.
- Additional bipartisan <u>legislation</u> focused on primary care would create a five-year pilot program to provide up to 100 FQHCs and RHCs with accredited continuing medical education and peer-to-peer clinical support to boost capacity in specific areas of medical need.

- CMMI engaged in a series of roundtable discussions over the last several months to collect stakeholder input on its strategic refresh, including topics such as health equity, including safety net providers, beneficiary engagement, and advanced primary care. More models are expected in the coming years that more explicitly focus on these priority areas.
- CMS has <u>signaled</u> it is planning to propose a new mandatory model possibly by the end of the year though it is not clear what the model would focus on. One possibility is that it will focus on Part B drug pricing, as CMS previously noted it has been considering small-scale Part B drug pricing demonstrations.

## Coverage and Affordability Improvements

States may lead in individual market reforms, though the Administration will continue to support



# **Policy Landscape**

The Inflation Reduction Act extended ACA premium tax credits through the 2025 plan year. The IRA also is intended to lower drug costs through negotiation and capping out-of-pocket costs. In August, HHS and the Treasury also released joint <u>final rules</u> to implement the No Surprises Act. HHS <u>announced</u> it is investing \$98.9 million in grant funding to 59 returning Navigator organizations for the 2023 Open Enrollment Period.

<b>Legislative Opportunities</b>
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#### At the state level, there are a variety of proposals to implement public option and Medicaid or BHP buy-in, though federal action is not likely in the near term.

 As mentioned, the Build Back Better Act included a plan to fix the Medicaid coverage gap. However, it is unlikely Democrats would be able to advance a fix successfully in the next Congress.

- The Departments of Labor, Health and Human Services, and Treasury issued a request for information (RFI) to inform future rulemaking for advanced explanation of benefits (AEOB) and good faith estimate (GFE) requirements of the No Surprises Act (NSA). A notice of proposed rulemaking establishing AEOB and GFE requirements is anticipated in January 2023. Comments to the RFI are due November 15, 2022.
- In concert with state-level initiatives to advance public options and other affordability measures, states may seek approval from the Biden Administration for 1332 waivers to secure pass-through savings.
- Per the <u>2022 notice of benefit and payment parameters</u>, HHS will likely propose specific standardized plan designs to be offered on the ACA Exchanges beginning in 2023.

#### **Nutrition**

Farm bill and CNR reauthorization could be legislative vehicles for initiatives in the Biden Administration's strategic plan



# **Policy Landscape**

The Biden-Administration released an ambitious <u>Strategic Plan</u> to end hunger and increase healthy eating and physical activity in the United States by 2030. The strategy identifies actions the Administration will pursue across five pillars: (1) Improving food access and affordability; (2) integrating nutrition and health; (3) empowering all consumers to make and have access to healthy choices; (4) supporting physical activity for all; and (5) enhancing nutrition and food security research.

#### **Legislative Opportunities**

#### The expiration of the Farm bill on September 30, 2023 presents an opportunity to update Supplemental Nutrition Assistance Program (SNAP) and other programs.

- The long overdue Child Nutrition
  Reauthorization (CNR) could also be an opportunity to incorporate lessons learned during the pandemic. Child nutrition programs include the National School Lunch Program and Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), among others.
- These reauthorization bills could also serve as a vehicle for policy recommendations included in the Administration's strategic plan.

## **Regulatory Opportunities**

The Biden Administration's regulatory agenda tees up several changes to nutrition programs.

- <u>Proposed rule</u> to revise the Child Nutrition Program meal patterns for meals and snacks to be consistent with the 2020 Dietary Guidelines for Americans (expected January 2023)
- <u>Final rule</u> to impose fines against schools or state agencies that fail to correct severe mismanagement or violations, set procedures for the termination and disqualification of organizations participating in the Summer Food Service Program, and require any institution or organization that has been terminated may not be authorized to administer other similar program (expected May 2023)
- <u>Final rule</u> to require school food authorities to provide the same level of financial support for lunches served to students who are not eligible for free or reduced-price lunches as is provided for lunches served to students eligible for free lunches and requires that all food sold in a school and purchased with funds from the nonprofit school food service account other than meals and supplements must generate revenue at least proportionate to the cost (expected May 2024)



Appendix A – Additional Drug Pricing Considerations

# IRA Final Provisions and Implementation Timeline



Provision	Implementation Date
Drug Price Negotiations	Negotiations process begins 2023, first price applicability year is 2026. More detail on the next slide.
Inflation Rebates for Medicare Only	Part D - October 1, 2022, with a January 2021 benchmark date.  Part B - January 1, 2023, with a January 2021 benchmark date
Insulin Copay Cap for Medicare Beneficiaries	Beginning plan year 2023
Beneficiary Annual \$2,000 OOP Cap	January 1, 2025, with cost-sharing in the catastrophic phase eliminated in 2024
Part D Redesign	Begins January 1, 2025. Manufacturer liability would be 10 percent in the initial coverage phase and 20 percent in the catastrophic phase.

# **Detailed Negotiations Timeline**





 HHS Secretary to publish a selected drugs list of 10 Part D negotiation eligible drugs



 Manufacturers must submit information on the non-FAMP of the negotiationeligible product



 The HHS secretary will make an initial maximum fair price offer based on years off patent and non-FAMP



Negotiations must be concluded by this date.

#### Septembe 1, 2024

• The HHS Secretary will publish in the Federal Register the maximum fair price

March 1 2025

 The HHS Secretary publishes an explanation for the maximum fair prices for each selected drug



The negotiated maximum fair price will go into effect

# Part B Inflation Rebates Payment Timeline





- Manufacturers will owe their first Part B inflation rebates to HHS 30-days following receiving the notice from HHS regarding any amounts owed for drugs whose prices have increased faster than inflation.
- Manufacturers will receive this notice from HHS no later than 6 months following the end
  of each calendar quarter beginning on or after Jan. 1, 2023.
- A breakdown of this for the first applicable period is below.

Point in Process	Timeframe	Relevant Date(s)
First colondar quarter	Consists of 2 month poriod	Begins Jan. 1, 2023
First calendar quarter	Consists of 3-month period	Ends March 31, 2023
HHS sends notice to manufacturers of rebates owed	Occurs 6 months following end of first calendar quarter	Oct. 1, 2023 (i.e., 6 months following March 31, 2023)
Manufacturers owe Part B rebates to HHS	30-days following receipt of notice from HHS	Oct. 31, 2023

# Part D Inflation Rebates Payment Timeline





- Manufacturers will owe their first Part D inflation rebates to HHS 30-days following receiving the notice from HHS regarding any amounts owed for drugs whose prices have increased faster than inflation.
- Manufacturers will receive this notice from HHS no later than 9 months following the end
  of each applicable period.
- A breakdown of this for the first applicable period is below.

Point in Process	Timeframe	Relevant Date(s)
First applicable period	Consists of 12-month period	Begins Oct. 1, 2022
First applicable period Consists of 12-month p	Consists of 12-month period	Ends Oct. 1, 2023
HHS sends notice to manufacturers of rebates owed	Occurs 9 months following end of first applicable period	July 1, 2024 (i.e., 9 months following Oct. 1, 2023)
Manufacturers owe Part D rebates to HHS	30-days following receipt of notice from HHS	July 31, 2024

# Potential for Drug Pricing Reform Post-Mid Term Election



The appetite for additional legislative action on drug pricing will likely be low in the next Congress, however, the Biden Administration will likely to turn to regulatory levers to advance health reforms if Republicans take control of Congress

## Legislative Actions

#### **PBM Reform**

 Given the recently approved FTC study to examine PBM practices, it is likely that the findings could be leveraged to address such practices in legislation.

# Anticompetitive Practices

 Practices such as pay-fordelay, patent thickets, and rebate walls have been included in previous drug pricing legislation and could be reexamined

## **Regulatory Actions**

#### **Drug Importation**

 HHS could begin to approve state importation programs

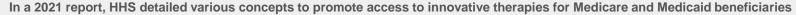
# Small Scale Mandatory Models

 This could feature a small-scale mandatory model for Part B drugs that links payments to improved patient outcomes, reduction on health disparities, patient affordability, and lower overall costs

# Total cost of care models that include drug costs

- Current total cost of care models, such as Affordable Care Organization (ACOs), only incorporate Part A and Part B costs into their benchmarks.
- To incentivize selecting lower cost pharmaceuticals, Part D costs could also be incorporated into the ACO benchmarks.

## Potential CMMI Models to Lower Drug Costs and Promote Access





A small scale, mandatory Part B model that would link payments for drugs to value-based outcome measures A Part D model that draws on the ongoing Senior Savings model for insulin and expands it to other high-cost drug classes

An accountable care model that includes Part D spending in spending benchmarks for purposes of shared savings calculations