This Week in Health Policy, Congressional Lookback, Regulatory Lookback, Comment & Application Deadlines

Wynne Health Group Weekly



2022 MIDTERM ELECTIONS PREVIEW

The upcoming elections on Tuesday, November 8, are the first midterms under President Joe Biden's tenure. The political stakes are particularly high for the Biden Administration, as Democrats are at risk of losing control of Congress. At the moment, Democrats are slightly favored to win the Senate, while Republicans are slightly favored to with the House. A split Congress could significantly impede the Administration's legislative agenda, therefore limiting policymaking through regulations.

Top voter priorities include economic issues, access to abortion and reproductive rights, and immigration issues. On the campaign trail, Democrats are discussing a slate of health-related issues, including access to abortion, COVID-19, workforce shortage, telehealth waiver extension, Affordable Care Act, drug pricing reforms, mental health, and health equity. Republicans are mostly focused on inflation and the economy, though there may be some discussion on telehealth waiver extensions, workforce shortage, vaccination mandates, and mental health.

Please see our 2022 midterm elections preview deck for more details.

<u>House</u>

Democrats currently have a 9-vote majority in the House (221-212 with two vacancies). All House seats are up for re-election. 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). Republicans will need to gain six seats to win the majority in the House.

Due mainly to retirements, we expect to see leadership changes in key House Committees. For example, three members are vying for the position of top Republican on the House Ways and Means Committee, due to the retirement of Rep Kevin Brady (R-TX). We also expect leadership changes in the House Budget Committee and House Oversight and Reform Committee.

<u>Senate</u>

The Senate is currently 50-50, with Vice President Harris as the tie-breaker. 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). Democrats cannot afford to net a single loss in order to keep control of the Senate.

Sen. Patty Murray (D-VA) is anticipated to become the top Democrats on the Senate Appropriations Committee, following the retirement of Sen. Pat Leahy (D-VT). If Sen. Murray becomes chair of the Appropriations Committee, then Sen Bernie Sanders (I-VT) is next in lead to lead the Senate Health, Education, Labor and Pensions (HELP) Committee. However, he would likely have to decide between leading the Senate Budget Committee or the HELP Committee. 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.

Policy Outlook

Legislative dynamics following the passage of the Inflation Reduction Act and leading up to the midterm elections have muddled 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 (P.L. 116-22). Also, the deadline for FY 2024 appropriations and Farm Bill.
- Dec. 31, 2023: Expiration of various Medicare extenders (e.g., Medicare patient IVIG access demonstration project; independence at home medical practice demonstration program).

In our <u>2022 midterm elections preview deck</u>, we discuss potential policymaking in the following areas:

- Climate and health
- Behavioral health
- Public health
- Health equity, maternal health, reproductive rights
- Medicaid reform
- Medicare reform
- Cost control
- Delivery reform/primary care
- Coverage/affordability improvements
- Nutrition

THIS WEEK IN HEALTH POLICY

Mon. (10/17)

- 12:00pm HHS Meeting: HIV/AIDS The Department of Health and Human Services (HHS) holds a meeting of the Presidential Advisory Council on HIV/AIDS to provide advice, information, and recommendations to the Secretary regarding programs and policies intended to promote effective HIV diagnosis, treatment, prevention, and quality care services. <u>Details</u>.
- 12:00pm Discussion: AEI The American Enterprise Institute (AEI) for Public Policy Research holds a virtual discussion on "Price Transparency in Health Care: A Report from the Field." <u>Details</u>.
- 3:00pm Discussion: BPC The Bipartisan Policy Center (BPC) holds a virtual discussion on new telehealth policies to promote better value and outcomes in the Medicare program. <u>Details</u>.

Tue. (10/18)

• 9:30am – NIH Meeting: Women's Health – The National Institutes of Health (NIH) holds a meeting of the Advisory Committee on Research on Women's Health for members to give advice and recommendations on priority issues affecting women's health and sex differences research. Topics to be discussed include climate change and the environmental impact on women's health. Details.

Wed. (10/19)

• 9:00am – HHS/CDC Meeting: Community Preventative Services – HHS and the Centers for Disease Control and Prevention (CDC) hold a meeting of the Community Preventive Services Task Force to deliberate on systemic reviews of literature and discuss topics including mental health, nutrition, and social determinants of health. <u>Details</u>.

• **10:30am – ONC Meeting: Public Health Data Systems** – The Office of the National Coordinator for Health IT (ONC) holds a meeting of the Public Health Data Systems Task Force 2022 to identify and prioritize policy and technical gaps associated with information systems relevant to public health and identify improvements that can be made. <u>Details</u>.

• **12:00pm – Discussion: The AHP –** The Alliance for Health Policy (AHP) holds a virtual discussion exploring the health market competition ecosystem, including current legislative and administrative policy levers and lessons learned at the state and federal level. Event sponsored by Arnold Ventures. <u>Details</u>.

• **3:30pm – Discussion: Brookings –** The Brookings Institution holds a virtual discussion titled, "The socioeconomic consequences of COVID-19 for Latino families." <u>Details</u>.

Additional Multi-Day Events

• **October 16-October 22 – HHS Meeting: Hypertension –** HHS Office on Women's Health holds a Hypertension Summit to discuss innovations and evidence to bridge practice gaps in the field of hypertension treatment and prevention. <u>Details</u>.

• October 19-October 20 - 11:00am – HHS Meeting: Human Research Protection – HHS holds a meeting of the Secretary's Advisory Committee on Human Research Protections to discuss ethical and regulatory considerations for the use of artificial intelligence in human subjects research. <u>Details</u>.

FEATURED WHG ANALYSIS

- WHG Roundup of CMS information releases on long-term services and supports and children's health In the Policy Hub Insight Bank <u>here</u>.
- Blog on President Biden's Executive Order Protecting Access to Reproductive Health Services On the Commonwealth Fund's To the Point <u>here</u>.
- WHG Roundup of Recent Telehealth Policy In the Policy Hub Insight Bank here.
- WHG Regulatory Outlook Summer 2022 Update In the Policy Hub Insight Bank here.
- WHG Issue Brief on the Nutrition Policy Landscape In the Policy Hub Insight Bank here.
- WHG A Suite Of Potential Executive Actions For A Post-Roe World In the Policy Hub Insight Bank here.

REGULATORY LOOKBACK

<u>Fri. (10/14)</u>

- Former FDA Commissioners <u>authored</u> a JAMA article on the need for FDA reforms, including oversight of diagnostic tests, dietary supplement, and cosmetics. <u>Details</u>.
- **President Biden** <u>issued</u> an executive order on lowering prescription drug <u>costs</u> for Americans. <u>Details</u>.

Thurs. (10/13)

 The FDA <u>issued</u> a request for public comments on a recently released <u>discussion paper</u> on areas associated with Distributed Manufacturing (DM) and Point-of-Care (POC) manufacturing. Comments are due December 13. <u>Details</u>.

Weds. (10/12)

- CMS released its vision of Medicare coverage for new and emerging technologies. Details.
- **The USPSTF** released final recommendations for <u>anxiety</u> and <u>depression and suicide</u> <u>risk</u> screening in children and adolescents. <u>Details</u>.
- The USDA <u>announced</u> that the agency is awarding \$110 million in grants to improve health care facilities in rural towns across the U.S. <u>Details</u>.
- **HHS** <u>announced</u> the establishment of the Medicare Drug Rebate and Negotiations Group within the Center for Medicare to implement IRA provisions. <u>Details</u>.
- **The OMH** <u>announced</u> more than \$4.8 million in grants to 10 organizations under its Community-Driven Approaches to Address Factors Contributing to Structural Racism in Public Health initiative. <u>Details</u>.

<u>Tues. (10/11)</u>

- **The Treasury and IRS** issued a <u>final rule</u> to revise criteria for ACA premium tax credit eligibility in the individual market. <u>Details</u>.
- The FNS <u>announced</u> that the Biden Administration released \$50 million in grant funding to states for schools to invest in new food service equipment. <u>Details</u>.

COMMENT & APPLICATION DEADLINES

- October 17: The USPSTF released draft recommendations and evidence reviews for screening for <u>anxiety</u> and <u>depression and suicide risk</u> in adults. <u>Details</u>.
- October 19: The FDA issued a request for applications from patient advocates interested in participating on the Patient Engagement Collaborative (PEC). Details.
- October 25: SAMHSA <u>announced</u> a new \$35 million grant opportunity to further support the 988 Suicide and Crisis Lifeline. <u>Details</u>.
- **October 26:** The FDA <u>issued</u> a proposed rule to establish requirements for a nonprescription drug product with an additional condition for nonprescription use (ACNU). <u>Details</u>.
- October 27: CMS is considering modifying one of the requirements states must follow to receive a temporary 6.2 percentage point increase in the federal Medicaid matching fund. CMS is reopening the public comment period for the interim final rule (IFR) that established these requirements in November 2020. <u>Details</u>.
- **October 31:** A group of eight House representatives are <u>seeking</u> input on how to improve upon the Medicare Access and CHIP Reauthorization Act (MACRA). <u>Details</u>.
- **November 4:** CMS issued a <u>Request for Information</u> seeking public input and feedback on issues related to health equity. <u>Details</u>.
- **November 4:** The Department of the Treasury <u>released</u> a set of RFIs to inform the implementation of the Inflation Reduction Act's clean energy incentives. <u>Details</u>.
- **November 6:** CMS <u>released</u> a proposed rule entitled, "Streamlining the Medicaid, Children's Health Insurance Program, and Basic Health Program Application, Eligibility Determination, Enrollment and Renewal Processes". <u>Details</u>.
- **November 14:** FDA <u>issued</u> draft guidance on computer software assurance for production and quality system assurance. <u>Details</u>.
- **November 15:** The Departments of Labor, HHS, and Treasury <u>issued</u> a RFI to inform future rulemaking for advanced explanation of benefits (AEOB) and good faith estimate (GFE) requirements. <u>Details</u>.
- **November 15:** The AHRQ <u>issued</u> a RFI on the current state of comprehensive, longitudinal, person-centered care planning for people with Multiple Chronic Conditions. <u>Details</u>.
- December 6: CMS issued an RFI on the current state of health care provider directories. Details.
- **December 7:** The FDA <u>issued</u> revised draft guidance on general clinical pharmacology considerations for pediatric studies of drugs. <u>Details</u>.

- **December 13:** The FDA <u>issued</u> a request for public comments on a recently released <u>discussion</u> <u>paper</u> on areas associated with Distributed Manufacturing (DM) and Point-of-Care (POC) manufacturing. <u>Details</u>.
- **December 31:** AHRQ <u>issued</u> a supplemental solicitation for nominations of members from Populations Underrepresented in Medicine (URIM) to serve on the Initial Review Group (IRG). <u>Details</u>.
- January 9: AHRQ announced a challenge competition to explore the resources and infrastructure needed to integrate real-world data from healthcare systems into systematic review findings. Details.

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