<u>This Week in Health Policy</u>, <u>Congressional Lookback</u>, <u>Regulatory Lookback</u>, <u>Comment & Application</u> Deadlines

Wynne Health Group Weekly



FRAMING THE WEEK

You're Invited - WHG 5-Year Anniversary Party

Please join us at our DC office on December 1st to celebrate Wynne Health Group's 5-Year Anniversary and the holiday season. RSVP and view more information <u>here</u>. We hope to see you there!

Election Preview

The 2022 Midterm Elections are tomorrow. Democrats remain at risk of losing control of Congress, especially in the House where polls indicate that Republicans have a decisive advantage. The race in the Senate remains neck and neck. Experts attribute the public's growing concern with the economy as a strong motivator for potentially steering more voters away from Democrats. The Federal Reserve most recently increased interest rates again on November 2 as inflation has remained elevated, though the U.S. notably added over 250,000 jobs in October. Still, growing uncertainty both domestically and abroad may have some voters seeking new leadership at the federal level.

Regardless of the outcome, substantial legislative action on health care remains unlikely in the next Congress. In a divided Congress, Democrats and Republicans may find bipartisan areas of overlap to be in short supply aside from current priority issues such as mental health. In a Republican-controlled Congress, even if Republicans are able to advance partisan legislation through, they will still be faced with the veto power of the presidency.

Additional perspective on potential shifts in House and Senate dynamics follow.

House

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. If the Republicans do take the House, Republican Leader Kevin McCarthy is widely expected to take the Speaker position, with Congressman Steve Scalise moving into the Majority Leader role. The position for Majority Whip is a race between NRCC Chair Tom Emmer (R-MO), Rep Jim Banks (R-IN) and Rep. Drew Ferguson (R-GA).

Senate

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. 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.

THIS WEEK IN HEALTH POLICY

Mon. (11/07)

• 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. Details.

Tue. (111/08)

• 2022 Midterm Elections

Wed. (11/09)

- 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. Details.
- 1:00pm HHS Webinar: Environmental Justice Index The Department of Health and Human Services (HHS) Office of Environmental Justice (OEJ), in conjunction with the Centers for Disease Control and Prevention (CDC)'s Agency for Toxic Substances and Disease Registry (ATSDR) hold a webinar that will teach attendees how to use the new Environmental Justice Index. Details.

Thurs. (11/10)

- 9:00am FDA Meeting: Ophthalmic Devices The Food and Drug Administration (FDA) holds a meeting of the Medical Devices Advisory Committee's Ophthalmic Devices Panel to provide advice and recommendations to the Agency on regulatory issues. Details.
- 10:00am ONC Meeting: HITAC ONC holds a meeting of the Health IT Advisory Committee to discuss recommendations on interoperability, privacy and security, patient access, and the use of technologies that support public health. <u>Details</u>.

Additional Multi-Day Events

 November 9-November 10 – CDC Meeting: Clinical Laboratory/Monkeypox – The Centers for Disease Control and Prevention (CDC) hold a meeting of the Clinical Laboratory Improvement Advisory Committee (CLIAC) to discuss the clinical and public health response to the monkeypox outbreak. Details.

FEATURED WHG ANALYSIS

- WHG Roundup of Recent Reproductive Health Developments In the Policy Hub Insight Bank here.
- WHG 2022 Midterm Elections Preview In the Policy Hub Insight Bank here.
- WHG Tracker of Climate Change Provisions in the IRA In the Policy Hub Insight Bank here.
- WHG Roundup of CMS information releases on long-term services and supports and children's health In the Policy Hub Insight Bank here.
- Blog on President Biden's Executive Order Protecting Access to Reproductive Health Services On the Commonwealth Fund's To the Point here.
- WHG Roundup of Recent Telehealth Policy In the Policy Hub Insight Bank here.

CONGRESSIONAL LOOKBACK

Fri. (11/4)

- MedPAC <u>convened</u> virtually for Day Two of its November 2022 public meeting and held sessions on safety-net hospital and standardizing MA supplemental benefits. All WHG session summaries are available on Policy Hub here.
- Sen. Wyden <u>released</u> a report on deceptive marketing practices in Medicare Advantage. <u>Details</u>.

Thurs. (11/3)

MedPAC <u>convened</u> virtually for Day One of its November 2022 public meeting and held sessions
on race and ethnicity data, a PAC PPS prototype, site neutral payments, and alternative payment
models for primary care. All WHG session summaries are available on Policy Hub <u>here</u>.

REGULATORY LOOKBACK

Thus (11/3)

CMS <u>released</u> an updated data snapshot of Medicaid and CHIP during the COVID-19 PHE.
 Details.

Weds. (11/2)

- CMS <u>held</u> a quarterly National Stakeholder Call with CMS Administrator Chiquita Brooks-LaSure.
 Details.
- **The FDA** <u>released</u> final guidance on cross labeling oncology drugs in combination regimens. <u>Details</u>.

Tues. (11/1)

- CMS <u>released</u> the CY 2023 MPFS final rule. <u>Details</u>.
- CMS released the CY 2023 HOPPS final rule. Details.
- HRSA <u>issued</u> an RFI on a proposed update to the Periodicity Schedule of the Bright Futures Recommendations for Pediatric Preventive Health Care. Comments are due December 2. <u>Details</u>.

Mon. (10/31)

- CMS <u>released</u> the CY 2023 ESRD PPS final rule. <u>Details</u>.
- CMS <u>released</u> the CY HH PPS final rule. <u>Details</u>.
- **The FDA** <u>issued</u> draft guidance on measuring growth and evaluating pubertal development in pediatric clinical trials. <u>Details</u>.

COMMENT & APPLICATION DEADLINES

 November 11: CMS is <u>seeking</u> nominations for a TEP focused on refining the nursing home antipsychotic medication measures. Details.

- November 14: FDA <u>issued</u> draft guidance on computer software assurance for production and quality system assurance. Details.
- 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>.
- **November 25:** 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>.
- **December 2:** HHS <u>issued</u> a request for written comments on proposed Healthy People 2030 objectives. <u>Details</u>.
- **December 2:** HRSA <u>issued</u> an RFI on a proposed update to the Periodicity Schedule of the Bright Futures Recommendations for Pediatric Preventive Health Care. <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. Details.
- December 20: The FDA <u>issued</u> draft guidance on proposed select updates for the Breakthrough Devices Program Guidance. Details.
- December 29: The CDC is <u>seeking</u> nominations for membership on the Advisory Committee on Breast Cancer in Young Women (ACBCYW). <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). Details.
- **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.

WHG Contacts for Inquiries

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