

Wynne Health Group Weekly



FRAMING THE WEEK

This week, the House continues to mark up their legislative recommendations for the \$3.5 trillion budget reconciliation package. Recommendations are due this Wednesday, September 15, but that date is non-binding. House and Senate Democrats intend to pre-conference their bill before floor votes to help move the process along. However, the timing of the votes remains unclear given a slew of issues – e.g., Sen. Joe Manchin’s [current opposition](#) to the size of the package and the looming September 30 deadline to fund the government for fiscal year (FY) 2022.

Today, the House Energy and Commerce (E&C) Committee will [mark up](#) its legislative recommendations for the Build Back Better Act budget reconciliation package. The FY 2022 budget resolution ([S.Con.Res. 14](#)) directs E&C to increase the deficit by not more than \$486 billion over FYs 2022 through 2031. Health care-related priorities in the recommendations include:

- H.R. 3 prescription drug reforms, including drug price negotiations, Part D redesign and an annual out-of-pocket cap, inflation rebates, and repealing the Trump Administration rebate rule;
- Adding dental, vision, and hearing coverage to Medicare;
- Closing the Medicaid coverage gap (starting with Marketplace premium tax credits (PTCs) and cost-sharing reduction assistance for eligible individuals through FY 2024, followed by a federal Medicaid program beginning FY 2025) and making the Children Health Insurance Program (CHIP) permanent;
- Creating an Affordable Care Act (ACA) reinsurance program to reduce healthcare premiums;
- Expanding access to home and community-based services (HCBS); and
- Investing in the public health infrastructure and workforce, as well as public health preparedness.

Tomorrow, the House Ways and Means (W&M) Committee will continue its [markup](#) of its legislative recommendations. They include prescription drug pricing reforms that mirror E&C’s recommendations as well as provisions to make permanent the recent changes to Marketplace PTCs by the American Rescue Plan Act of 2021 ([P.L. 117-2](#)). Last week, W&M approved its first set of legislative recommendation, which include:

- Expanding Medicare coverage to include dental benefits (available January 1, 2028); vision benefits (available October 1, 2022); and hearing benefits (available October 1, 2023);
- Improving the quality of care delivered by skilled nursing facilities by increased funding to address staffing shortages, enhance the accuracy and reliability of quality data, prevent elder abuse; and
- Bolstering the health care workforce through the Health Profession Opportunity Grant (HPOG) program.

THIS WEEK IN HEALTH POLICY

Mon. (9/13)

- **10:30am – NIH Meeting: Allergy and Infectious Disease** – The National Institutes of Health (NIH) National Institute of Allergy and Infectious Diseases holds a meeting of the National Advisory Allergy and Infectious Diseases Council to hear from the Institute Director. [Details](#).
- **11:00am – Markup: Budget Reconciliation** – The House Energy and Commerce Committee marks up its legislative recommendation for the Build Back Better Act. [Details](#).
- **11:45am – NIH Meeting: Environmental Health** – The NIH National Institute of Environmental Health Sciences holds a meeting of the National Advisory Environmental Health Sciences Council to hear the Director’s report and discuss program updates. [Details](#).
- **1:00pm – BPC Webinar: Food Security** – The Bipartisan Policy Center (BPC) holds a webinar titled, “Improving Food and Nutrition Security During COVID-19 and the Economic Recovery.” [Details](#).

Tue. (9/14)

- **9:00am – Markup: Budget Reconciliation** – The House Ways and Means Committee marks up its legislative recommendation for the Build Back Better Act. [Details](#).
- **11:00am – NIH Meeting: Nursing Research** – The NIH National Institute of Nursing Research holds a meeting of the National Advisory Council for Nursing Research to hear the Director’s report and discuss program updates. [Details](#).
- **12:00pm – NIH Meeting: Mental Health** – The NIH National Institute for Mental Health holds a meeting of the National Advisory Mental Health Council to hear the Director’s report and discuss program updates. [Details](#).
- **1:00pm – BPC Webinar: Long-Term Care** – The BPC holds a webinar titled, “Improving the Availability of Long-Term Care.” [Details](#).

Wed. (9/15)

- **8:00am – NIH Meeting: Aging** – The NIH National Institute on Aging holds a meeting of the National Advisory Council on Aging to hear the Director’s report and discuss program updates. [Details](#).
- **9:00am – Markup: Budget Reconciliation** – The House Ways and Means Committee marks up its legislative recommendation for the Build Back Better Act. [Details](#).
- **12:00pm – CMS Meeting: Outreach and Education** – The Centers for Medicare and Medicaid Services (CMS) Advisory Panel on Outreach and Education (APOE) holds a meeting to discuss opportunities to enhance the effectiveness of consumer education strategies concerning CMS programs. [Details](#).
- **12:45pm – NIH Meeting: Drug Abuse** – The NIH National Institute on Drug Abuse holds a meeting of the National Advisory Council on Drug Abuse to hear the Director’s report and discuss program updates. [Details](#).

Fri. (9/17)

- **8:30am – FDA Meeting: Pfizer COVID-19 Booster** – The Food and Drug Administration (FDA) Vaccines and Related Biological Products Advisory Committee holds a meeting to discuss the Pfizer-BioNTech application for the administration of a third (booster) dose of the COMIRNATY COVID-19 vaccine. [Details](#).
- **10:00am – FDA Meeting: Pediatric Safety** – The Food and Drug Administration (FDA) Pediatric Advisory Committee holds a meeting to discuss pediatric-focused safety reviews. [Details](#).

Additional Multi-Day Events

- **September 14-September 15 – HHS Meeting: Vaccines** – The Department of Health and Human Services (HHS) National Vaccine Advisory Committee holds a meeting to cover the most pressing topics affecting the vaccine enterprise. [Details](#).

- **September 14-September 15 – 9:00am – CDC/CMS Meeting: ICD-10** – The Centers for Disease Control and Prevention (CDC) and CMS hold a meeting of the National Center for Health Statistics ICD-10 Coordination and Maintenance Committee to discuss updates to the International Statistical Classification of Diseases and Related Health Problems (ICD-10). [Details.](#)
- **September 14-September 15 – 12:00pm – VA Meeting: Veteran Homelessness** – The Department of Veteran's Affairs (VA) holds a meeting of the Advisory Committee on Homeless Veterans to provide an assessment of the effectiveness of the policies, structures, and services of the VA in assisting veterans at risk of or experiencing homelessness. [Details.](#)
- **September 15-September 16 – 1:00pm – AHP Summit: Health Equity** – The Alliance for Health Policy (AHP) holds a Health Equity Summit to reflect on lessons learned from the COVID-19 pandemic and examine policies that contribute to inequity. [Details.](#)

FEATURED WHG ANALYSIS

- **WHG Side-by-Side of Medicaid Expansion Gap Bills** – In the Policy Hub Insight Bank [here.](#)
- **WHG Side-by-Side of Health Technology Assessment Models** – In the Policy Hub Insight Bank [here.](#)
- **WHG Updated 2021 Legislative and Regulatory Outlook** – In the Policy Hub Insight Bank [here.](#)
- **WHG Chart Key Federal Public Option Bills in the 117th Congress; Side-by-Side Comparison** – In the Policy Hub Insight Bank [here.](#)
- **WHG Overview of Recent Development on Federal Telehealth Policy** – In the Policy Hub Insight Bank [here.](#)
- **WHG Chart of the Major Drug Pricing Proposals in the 117th Congress** – In the Policy Hub Insight Bank [here.](#)

CONGRESSIONAL LOOKBACK

Thurs. (9/9)

- **The House E&C Committee** [released](#) its first set of legislative recommendations for the Build Back Better Act, Democrats' \$3.5 trillion budget reconciliation package. [Details.](#)

Wed. (9/8)

- **The House E&L Committee** [released](#) its budget reconciliation legislative recommendations, which includes a several nutrition provisions. [Details.](#)

Tues. (9/7)

- **The House W&M Committee** [released](#) its first set of legislative recommendations for the Build Back Better Act, Democrats' \$3.5 trillion budget reconciliation package. [Details.](#)
- **MACPAC** [released](#) three publications centering around behavioral health needs and services for youth and adults. [Details.](#)

REGULATORY LOOKBACK

Fri. (9/10)

- **HRSA** [announced](#) it is making \$22.5 billion in new funding available for health care providers affected by the COVID-19 pandemic. [Details.](#)
- **HRSA** [seeks](#) public comment on proposed updates to the Periodicity Schedule for HRSA's Bright Futures Program. Comments are due October 13. [Details.](#)

Thurs. (9/9)

- **HHS** [released](#) its Report to the White House Competition Council on its Comprehensive Plan for Addressing High Drug Prices. [Details.](#)

- **HHS [announced](#)** a new amendment to its March 2020 Declaration under the Public Readiness and Emergency Preparedness (PREP) Act to expand access to COVID-19 therapeutics. [Details.](#)
- **Chiquita Brooks-LaSure** wrote a blog post discussing her [vision](#) for the agency to mark her first 100 days as the CMS Administrator. [Details.](#)
- **CMS [announced](#)** they are distributing an additional \$452 million in “pass-through funding” from the ARP to support efforts to improve access to affordable and comprehensive health insurance coverage through section 1332 waivers creating state-based reinsurance programs. [Details.](#)

Wed. (9/8)

- **PCORI [announced](#)** funding opportunities with special areas of emphasis that include telehealth for chronic disease management and addressing racism and bias in healthcare systems and care delivery. Letters of intent are due October 5. [Details.](#)
- **CMS [announced](#)** flexibilities being provided to ensure New Jersey and New York residents’ access to health care in the wake of Hurricane Ida. [Details.](#)

Tues. (9/7)

- **The FDA** announced the launch of the [Novel Excipient Review Pilot Program](#) as a new pathway for manufacturers to obtain agency review of certain novel excipients. Proposals are due December 7. [Details.](#)
- **The CRS** released a [report](#) answering frequently asked questions (FAQs) about the Provider Relief Fund (PRF). [Details.](#)
- **The FDA [announced](#)** a request for nominations for members to serve on the Tobacco Products Scientific Advisory Committee. Nominations are due November 7. [Details.](#)
- **HHS OIG [published](#)** a report on the OIG’s audit to assess the completeness and accuracy of CMS COVID-19 data for nursing homes. [Details.](#)

COMMENT & APPLICATION DEADLINES

- **September 13:** CMS [released](#) its calendar year (CY) 2022 Medicare Physician Fee Schedule (MPFS) proposed rule. [Details.](#)
- **September 15:** The NIH Office of Research on Women’s Health [requests](#) comments to inform planning of the Women’s Health Consensus Conference. [Details.](#)
- **September 17:** The CDC [announced](#) it is seeking nominations for individuals to serve as members of the Healthcare Infection Control Practices Advisory Committee. [Details.](#)
- **September 17:** CMS [released](#) the CY 2022 Hospital Outpatient Prospective Payment System and ASC Payment System Proposed Rule. [Details.](#)
- **September 19:** HRSA [seeks comments](#) on draft updates to the [Women’s Preventive Services Guidelines](#). [Details.](#)
- **September 21:** HRSA [announced](#) a funding opportunity for the teaching Health Center Graduate Medical Education (THCGME) New and Expanded Residency Program. [Details.](#)
- **September 25:** The FDA [announced](#) a request for nominees to serve as voting or nonvoting consumer representatives on several agency advisory committees. [Details.](#)
- **September 28:** CMS [issued](#) a proposed rule that would authorize states to make payment to third parties, to facilitate easier access to employee benefits. [Details.](#)
- **October 5:** **PCORI [announced](#)** funding opportunities with special areas of emphasis that include telehealth for chronic disease management and addressing racism and bias in healthcare systems and care delivery. [Details.](#)
- **October 9:** CMS [issued](#) a proposed rule with rescind the Most Favored Nation (MFN) Model interim final rule. [Details.](#)
- **October 11:** The Department of Agriculture RHS [announced](#) available grant funding for the establishment of the Emergency Rural Health Care Grant Program. [Details.](#)
- **December 11:** The FDA [issued](#) a request for comments on issues related to the post-approval regulation of PANDAs. [Details.](#)

- **October 13:** HRSA [seeks](#) public comment on proposed updates to the Periodicity Schedule for HRSA's Bright Futures Program. [Details](#).
- **October 18:** The CDC [seeks comments](#) on two contraception guidance documents, which provide evidence-based recommendations to assist health care providers when counseling patients on contraceptive choice and use. [Details](#).
- **October 22:** The U.S. Citizenship and Immigration Services [announced](#) that it is seeking written comments and related materials regarding public charge inadmissibility. [Details](#).
- **November 7:** The FDA [announced](#) a request for nominations for members to serve on the Tobacco Products Scientific Advisory Committee. [Details](#).
- **December 7:** The FDA announced the launch of the [Novel Excipient Review Pilot Program](#) as a new pathway for manufacturers to obtain agency review of certain novel excipients. [Details](#).

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