

Wynne Health Group Weekly



FRAMING THE WEEK

Infrastructure

The Senate pushes to wrap up infrastructure this week before adjourning for summer recess. A vote on final passage of the nearly \$1 trillion bipartisan infrastructure package (including \$550 billion in new spending) has not yet been scheduled but is expected in the coming days. In the legislative text released last night, the health-related pay-fors are:

- **Extending the Medicare sequester by one year through fiscal year 2031.** Congress temporarily suspended the sequestration of Medicare from May 2020 through December 2021 ([P.L. 117-7](#)).
- **Requiring manufacturers to refund Medicare for the unused amounts of medication in a single-dose vial administered under Medicare's Part B, beginning January 1, 2023.** Refunds would be deposited into the Supplementary Medical Insurance (SMI) Trust Fund, which funds Part B and Part D. While the SMI Trust Fund is statutorily programmed to be funded through a combination of beneficiary premiums and general revenue transfers, this implies that beneficiary premiums will increase to the extent costs increase under Parts B and D. Costs are [expected](#) to increase as additional baby boomers continue aging into Medicare, especially through 2029.
- **Delaying implementation of the Trump-era Medicare Part D rebate rule until January 1, 2026.**

The infrastructure package does not use the Provider Relief Fund to offset its costs. However, the package would rescind unobligated COVID-19 appropriations from other accounts, such as economic injury disaster loan (EIDL) subsidies, pandemic relief for aviation workers, and the Education Stabilization Fund. The House-approved INVEST in America Act ([H.R. 3684](#)), which [passed](#) mostly along party lines, will be used as the vehicle for the Senate bipartisan infrastructure package.

Budget Reconciliation

After infrastructure, Senate Majority Leader Chuck Schumer (D-NY) plans to bring up the \$3.5 trillion fiscal year (FY) 2022 budget resolution that will establish reconciliation instructions, setting the guidelines for Democrats to pursue their legislative priorities – including making premium tax credit enhancements permanent; adding dental, vision, and hearing; drug pricing reform; and closing the Medicare expansion coverage gap.

Appropriations

The Senate Appropriations Committee will begin to mark up its **fiscal year (FY) 2022 spending bills**, starting with the funding for **Agriculture, Rural Developments, Food and Drug Administration, and**

Related Agencies. The House passed funding for these agencies as part of a seven-bill minibus ([H.R. 4502](#)), which also included funding for Labor, Health and Human Services, and Education.

Senate HELP Markup

Tomorrow, the Senate Health, Education, Labor and Pensions (HELP) Committee is expected to advance at an [executive session](#) a slate of **bipartisan bills related to suicide prevention, access to assistive technology, and reasonable accommodations for pregnant workers**. Given the bipartisan, bicameral support for these relative noncontroversial bills, we could these bills make their way to President Biden's desk for signature in the fall. The executive session will not be webcast.

- **Suicide Training and Awareness Nationally Delivered for Universal Prevention (STANDUP) Act (S. 1543)** would require state, tribal, and local educational agencies that receive grant funding for priority mental-health needs, including through the Project AWARE State Education Agency Grant Program, to establish and implement evidence-based suicide awareness and prevention training policies. **The House passed a substantively identical bill (H.R. 586) in May.**
- **Suicide Prevention Lifeline Improvement Act (S. 2425)** would increase funding for the suicide prevention hotline and authorize a pilot program on innovative technologies (e.g., social media, texting, and email) for suicide prevention. **The House passed a nearly identical bill (H.R. 2981) in May.** The main difference is the authorized funding amounts for the hotline – in the House bill, \$50 million for each of fiscal years (FYs) 2022 through 2024; and in the Senate bill, \$113.6 million for each of FYs 2022 through 2024.
- **21st Century Assistive Technology Act (S. 2401)** would increase access to [assistive technology services](#) (e.g., mobility aids, hearing aids, voice recognition programs) for individuals with disabilities of all ages through grants to state agencies, nonprofits, and other public organizations. There is no House companion bill.
- **Pregnant Workers Fairness Act (S. 1486)** would prohibit employment practices that discriminate against making reasonable accommodations for qualified employees affected by pregnancy, childbirth, or related medical conditions. **The House passed an identical bill (H.R. 1065) in May (315-101).**

THIS WEEK IN HEALTH POLICY

Mon. (8/2)

- **9:00am – NIH Listening Session: Addiction** – The National Institutes of Health (NIH) hosts a listening session to inform the proposed Advanced Research Projects for Health (ARPA-H) titled, “Advocates for Research on Addiction and Alcoholism.” [Details.](#)

Tue. (8/3)

- **TBD – Executive Session: Suicide Prevention, Assistive Technology** – The Senate Health, Education, Labor and Pensions Committee convenes an executive session to consider nominees and mark up bills related to suicide prevention ([S. 1543](#), [S. 2425](#)), assistive technology ([S. 2401](#)), and reasonable accommodations for pregnant workers ([S. 1486](#)). The meeting will not be webcast. [Details.](#)
- **12:00pm – NIH Listening Session: Diabetes, Kidney Disease, Maternal and Child Health, and Integrated Medicine** – The NIH convenes a listening session to inform ARPA-H titled, “Advocates for Research on Diabetes, Digestive Disorders and Kidney Disease, Child and Maternal Health, and Complementary and Integrated Medicine.” [Details.](#)

Wed. (8/4)

- **12:00pm – BPC Discussion: Telehealth** – The Bipartisan Policy Center (BPC) holds a virtual discussion titled, “Not Your Mother’s Healthcare: Surveying Consumer Experiences with Telehealth Services.” [Details](#).
- **12:30pm – Meeting: Toxicology** – The NIH holds a meeting of the National Toxicology Board of Scientific Counselors to discuss the Safe and Sustainable Alternatives Program and the Scientific Cyberinfrastructure Program. [Details](#).
- **2:00pm – NIH Listening Session: Biomedical Research and General Medicine** – The NIH convenes a listening session to inform ARPA-H titled, “Advocates for Biomedical and Translational Research and General Medicine.” [Details](#).

Thurs. (8/5)

- **10:00am – HRSA Meeting: Community-Based Linkages** – The Health Resources and Services Administration (HRSA) holds a virtual meeting of the Advisory Committee on Interdisciplinary, Community-Based Linkages to discuss the Health Professions Accreditors Collaborative, the 20th Report to Congress, and potential topics for fiscal year 2022. [Details](#).
- **10:30am – NIH Listening Session: Infectious Diseases and Global Health** – The NIH convenes a listening session to inform ARPA-H titled, “Advocates for Research on Allergies and Infectious Diseases and Global Health.” [Details](#).
- **12:00pm – NIH Meeting: Sleep Research** – The NIH holds a meeting of the National Heart, Lung, and Blood Institute for updates on the progress of sleep and circadian research activities. [Details](#).

Additional Multi-Day Events

- **August 3-August 4 – 1:00pm – HHS Meeting: HIV/AIDS** – The Department of Health and Human Services (HHS) holds a meeting of the Presidential Advisory Council on HIV/AIDS to discuss the report, “Ending the HIV Epidemic: A Plan for America and the Updated National HIV Strategy” and other items. [Details](#).

FEATURED WHG ANALYSIS

- ***NEW* 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. (7/29)

- **The E&C Subcommittee on Health** convened [hearing](#) to examine the current challenges to developing treatments and cures for neurodegenerative diseases. [Details](#).

Wed. (7/28)

- **The House E&L Subcommittee** held a [hearing](#) examining the WIC program and the Child and Adult Care Food Program. [Details](#).

REGULATORY LOOKBACK

Fri. (7/30)

- **The FDA [announced](#)** the FY 2022 rates for prescription drug user fees. [Details](#).
- **The FDA [issued](#)** a final rule to amend its medical product “intended use” regulations. [Details](#).
- **CMS [approved](#)** a SPA for California to extend COVID-19 emergency sick leave benefits for In-Home Supportive Services (IHSS) providers. [Details](#).
- **CMS [issued](#)** a proposed rule that would authorize states to make payment to third parties, to facilitate easier access to employee benefits. Comments are due September 28. [Details](#).

Thurs. (7/29)

- **CMS issued its [final rule](#)** for the FY 2022 Hospice Wage Index. [Details](#).
- **CMS issued its [final rule](#)** for the FY 2022 Inpatient Psychiatric Facility (IPF) PPS. [Details](#).
- **CMS issued its [final rule](#)** for the FY 2022 Skilled Nursing Facility (SNF) PPS. [Details](#).
- **CMS issued its [final rule](#)** for the FY 2022 Inpatient Rehabilitation Facility (IRF) PPS. [Details](#).

Wed. (7/28)

- **CMS [released](#)** new data from the Medicare Current Beneficiary Survey (MCBS) about Medicare beneficiaries and the COVID-19 pandemic. [Details](#).
- **HRSA [announced](#)** three new funding opportunities totaling approximately \$76 million to support community-based primary care medical and dental residency programs. [Details](#).
- **HHS [announced](#)** \$121 million in funding from the American Rescue Plan (ARP) to support COVID-19 vaccination efforts in underserved communities. [Details](#).

Mon. (7/26)

- **MACPAC** recently published a [compendium](#) of state coverage policies for adult mental health services. [Details](#).

COMMENT & APPLICATION DEADLINES

- **August 2:** FDA [issued](#) draft guidance on oral drug products administered via enteral feeding tube. Comments are due August 2. [Details](#).
- **August 6:** The White House ONDCP [issued](#) a request for information seeking feedback on whether and to what extent its policies and programs perpetuate systemic barriers to opportunities for underserved communities. [Details](#).
- **August 22:** The FDA [issued](#) a request for applications of patient advocates interested in participating on the Patient Engagement Collaborative. [Details](#).
- **August 27:** CMS [issued](#) the cycle year (CY) 2022 home health prospective payment system and rate update proposed rule. Comments are due August 27. [Details](#).
- **August 27:** PCORI [issued](#) a request for comment on its five national priorities for health that will serve as the foundation for developing PCORI’s Research Agenda. [Details](#).
- **August 27:** The FDA [issued](#) draft guidance entitled “Cancer Clinical Trial Eligibility Criteria: Approach to Available Therapy in Non-Curative Settings.” [Details](#).
- **August 30:** HRSA [announced](#) three funding opportunities totaling \$103 million from the American Rescue Plan Act to address mental health needs. [Details](#).
- **August 30:** HRSA [announced](#) a funding opportunity for the Teaching Health Center Planning and Development Program. [Details](#).
- **August 30:** HRSA [announced](#) a funding opportunity for Teaching Health Center Planning and Development Technical Assistance. [Details](#).
- **August 31:** The CDC [seeks](#) nominations for the CDC/Health Resources & Services Administration (HRSA) Advisory Committee on HIV, Viral Hepatitis, and STD Prevention and Treatment (CHACHSPT). [Details](#).
- **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 21:** HRSA [announced](#) a funding opportunity for the teaching Health Center Graduate Medical Education (THCGME) New and Expanded Residency Program. [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.](#)

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