

Wynne Health Group Weekly



FRAMING THE WEEK

With the Biden Administration's soft deadline of having a compromise on infrastructure solidified by Memorial Day, this could be the last week of consequential negotiations before the White House shifts to the Democrat-only budget reconciliation track. The White House and Senate Republicans remain far apart on fundamental issues – price tag, scope, and most crucially, pay-fors. Senate Republicans most recently rejected the White House's \$1.7 trillion infrastructure offer – about \$500 billion less than Biden's initial proposal and nearly a trillion more than Senate Republicans' top number. They have also maintained that pay-fors oriented around increasing the corporate tax rate are a nonstarter.

Beyond this, lawmakers will soon turn their attention to the **President's forthcoming fiscal year (FY) 2022 full budget request**. The Office of Management and Budget's (OMB) detailed budget proposal will kick off the appropriations process – a process that will look quite different this year with the return of "earmarks" (formally known as "community project funding"). Additionally, discretionary spending beginning FY 2022 is not subject to statutory spending caps.

Of additional note, the Supreme Court is [scheduled](#) to issue formal Opinions today and may rule on the **Affordable Care Act (ACA) lawsuit** (*Texas v. California*). Oral arguments on the case in November suggested the Court would allow the rest of the ACA to stand even if it finds the individual mandate to be unconstitutional ([details](#)).

President's FY 2022 Budget

OMB is expected to release its **full FY 2022 budget request** to Congress this Friday, May 28. Budget topline [released](#) in April gave legislators a broad sense for the White House's health care priorities – a request which totaled at \$131.7 billion for HHS and focused on public health modernization; research on diseases such as cancer, Alzheimer's, and diabetes; supports for mental health and substance use disorder; gun violence; health equity; maternal mortality; and the intersection of health and the environment. Additional detail on the Administration's vision for executing on each of these priorities is expected in the full request.

Members of Congress will also have the opportunity to glean more information on the public health- and research-focused components of the HHS budget in a set of hearings with the **National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC)** on Tuesday and Wednesday of this week, respectively. Legislative direction on improvements to maternal and mental health – a White House priority – will become clearer after Tuesday's markup of multiple maternal and mental health bills in the Senate Health, Education, Labor and Pensions (HELP) Committee.

The President's Budget is also expected to include additional detail on his envisioned new biomedical research agency, the **Advanced Researched Projects Agency for Health (ARPA-H)**. Reps. Diana DeGette (D-CO) and Fred Upton (R-MI) have expressed strong support for ARPA-H and suggested it may be included in a forthcoming Cures 2.0 package (April 2020 white paper [here](#)). Once the Administration's plans on ARPA-H are revealed, movement on a **new Cures 2.0 package** may materialize in the next several weeks.

Notably, the forthcoming budget request is no longer expected to include detail on major health care reform initiatives that were features of President Biden's campaign: **a federal public option program and drug pricing reform**. The omission of these items is reportedly intended to curb criticisms that the Administration is spending too excessively on new initiatives. Forgoing these priorities in the President's FY 2022 Budget appears to signal some hesitancy among White House officials to pursue Democrat-only legislation, especially as Biden's infrastructure proposal will likely move through budget reconciliation.

Senate Floor Activity

The Senate is slated to vote on the confirmation for Chiquita Brooks-LaSure as the **Centers for Medicare & Medicaid Services (CMS) Administrator** as soon as tomorrow after attempts from Senate Republicans to stall her nomination over the Biden Administration's revocation of Texas's Medicaid waiver. Brooks-LaSure is expected to be confirmed.

This week, the Senate will continue consideration of the U.S. Innovation and Competition Act ([S. 1260](#)) (formerly known as the "Endless Frontier Act") – a bipartisan bill aimed at increasing the United States' technological competitiveness. It includes funding to expand the capacity of the National Science Foundation (NSF) and the National Institutes of Standards and Technology (NIST) in various areas, including **biotechnology, medical technology, genomics, and synthetic biology**. Under the new amendment proposed by Senate Majority Leader Chuck Schumer (D-NY), the bill would expand the 5G broadband network, a pressing need amid the increased demand for telehealth and remote working and learning during the COVID-19 pandemic.

THIS WEEK IN HEALTH POLICY

Tue. (5/25)

- **10:00am – Markup: Maternal Health and Mental Health** – The Senate Health, Education, Labor and Pensions Committee convenes an executive session to consider bills focused on maternal health, mental health, among other health issues. [Details.](#)
- **10:00am – Hearing: FY 2022 NIH Budget** – The House Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies convenes a hearing titled, "FY 2022 Budget Request for the National Institutes of Health." [Details.](#)
- **11:30am – Hearing: Drinking Water** – The House Energy and Commerce Subcommittee on Environment and Climate Change convenes a hearing titled, "The CLEAN Future Act and Drinking Water: Legislation to Ensure Drinking Water is Safe and Clean." [Details.](#)
- **2:30pm – Hearing: Gun Violence** – The Senate Judiciary Subcommittee on The Constitution convenes a hearing titled, "Stop Gun Violence: Safe Storage." [Details.](#)

Wed. (5/26)

- **10:00am – Hearing: FY 2022 NIH Budget** – The Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies convenes a hearing titled, "National Institutes of Health's FY22 Budget and the State of Medical Research." [Details.](#)
- **10:00am – Hearing: FY 2022 CDC Budget** – The House Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies convenes a hearing titled, "FY 2022 Budget Request for the Centers for Disease Control and Prevention." [Details.](#)
- **11:30am – Hearing: COVID-19 Vaccine** – The House Energy and Commerce Subcommittee on Oversight and Investigations convenes a hearing titled, "A Shot at Normalcy: Building COVID-19 Vaccine Confidence." [Details.](#)
- **12:00pm – Hearing: Nutrition** – The House Agriculture Committee convenes a hearing titled, "The Future of SNAP: Moving Past the Pandemic." [Details.](#)

Thurs. (5/27)

- **10:00am – Hearing: Child Care** – The House Ways and Means Subcommittee on Worker and Family Support convenes a legislative hearing on "Universal Paid Leave and Guaranteed Access to Child Care." [Details.](#)

- **12:00pm – Hearing: Dislocated Workers** – The House Education and Labor Subcommittee on Higher Education and Workforce Investment titled, “Workforce Innovation and Opportunity Act Reauthorization: Creating Employment Pathways for Dislocated Workers.” [Details](#).

Fri. (5/28)

- **TBD – President’s Budget** – The Biden Administration is scheduled to release President Biden’s FY 2022 budget.
- **2:00pm-6:00pm – HHS Meeting: COVID-19** – HHS convenes a meeting of the COVID-19 Health Equity Task Force. [Details](#).

FEATURED WHG ANALYSIS

- **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](#).
- **WHG Round of Key CMMI Developments** – In the Policy Hub Insight Bank [here](#).
- **WHG Catalogue of COVID-19 Government Response** – April Edition – In the Policy Hub Insight Bank [here](#).
- **Summary of Recent Federal Actions on Maternal Health & Gender Equity** – In the Policy Hub Insight Bank [here](#).
- **Prospects for Drug Pricing Reform Under a Biden-Harris Administration** – Featured on The Commonwealth Fund’s *To the Point* [here](#).

CONGRESSIONAL LOOKBACK

Thurs. (5/20)

- **Senate HELP** Subcommittee on Primary Health and Retirement Security convened a [hearing](#) to discuss policy solutions to address the health care workforce shortage. [Details](#).
- **Senate Committee on Aging** [convened](#) a hearing to explore ways to address Alzheimer’s disease and the challenges that caregivers face in supporting family members and patients with the disease. [Details](#).

Tues. (5/18)

- **The House Committee on Oversight and Reform** [convened](#) a hearing to examine AbbVie’s pricing mechanisms for its top two selling drugs, Humira, an anti-inflammatory drug, and Imbruvica, a cancer drug. [Details](#).

REGULATORY LOOKBACK

Fri. (5/21)

- **CMS** [released](#) an updated data snapshot detailing the impact of COVID-19 on Medicare beneficiaries. [Details](#).
- **The FTC** [issued](#) a request for public feedback to inform their review of how to best update their approaches to analyzing the effects of pharmaceutical mergers. Comments are due June 25. [Details](#).
- **The FDA** [issued](#) draft guidance on adjusting covariates in randomized clinical trials for drugs and biological products. [Details](#).

Thurs. (5/20)

- **The FDA** [issued](#) final guidance on peripheral vascular atherectomy device premarket notification submissions. [Details](#).

Wed. (5/19)

- **The FDA [issued](#)** draft guidance on feasibility and early feasibility clinical studies for medical devices intended to improve glycemic control in patients with Type 2 diabetes mellitus (T2DM). Comments due July 19. [Details](#).
- **HHS [announced](#)** it is distributing \$3 billion in funding through the SAMHSA address the rise in mental illness and substance use disorder (SUD). [Details](#).
- **ASPR [requests input](#)** to inform the use of new funding for the [Medical Reserve Corps \(MRC\)](#). Comments due June 19. [Details](#).
- **The USPSTF [issued](#)** a final recommendation statement in favor of screening for colorectal cancer in adults aged 45 to 75 years. [Details](#).

Tues. (5/18)

- **The FDA [issued](#)** final guidance on developing drugs and biological products for the treatment or prevention of COVID-19. [Details](#).

COMMENT & APPLICATION DEADLINES

- **May 24:** The FDA [issued](#) draft and revised draft product-specific guidances. [Details](#).
- **May 28:** CMS [announced](#) it is seeking nominations for a TEP that will support the development and refinement of PAC quality measures addressing function. [Details](#).
- **June 1:** AHRQ [announced](#) it is seeking nominations for members to serve on an initial review group (IRG) for scientific peer review of AHRQ grant applications. [Details](#).
- **June 4:** USDA [announced](#) that it is accepting applications for Distance Learning and Telemedicine (DLT) program grants to help provide educational and medical services in rural areas. [Details](#).
- **June 7:** CMS [released](#) its proposed rule for the fiscal year (FY) 2022 Inpatient Psychiatric Facility (IPF) Prospective Payment System (PPS) ([fact sheet](#)). [Details](#).
- **June 7:** CMS [released](#) the fiscal year (FY) 2022 inpatient rehabilitation facility (IRF) prospective payment system (PPS) proposed rule ([press release](#)). [Details](#).
- **June 7:** CMS released its [proposed rule](#) for the fiscal year (FY) 2022 Skilled Nursing Facility (SNF) Prospective Payment System (PPS) ([fact sheet](#)). [Details](#).
- **June 7:** CMS released its FY 2022 Hospice Wage Index [proposed rule](#) ([fact sheet](#)). [Details](#).
- **June 11:** CMS [issued](#) a notice of funding opportunity for its Minority Research Grant Program. [Details](#).
- **June 11:** CMS [announced](#) it is seeking nominations for the Advisory Panel on Outreach and Education (APOE). [Details](#).
- **June 16:** The AHRQ [issued](#) an FOA for research projects that test promising digital healthcare interventions at the point of care. [Details](#).
- **June 18:** Payer application deadline for the [Primary Care First Model](#). [Details](#).
- **June 25:** The FTC [issued](#) a request for public feedback to inform their review of how to best update their approaches to analyzing the effects of pharmaceutical mergers. [Details](#).
- **June 26:** The FDA [issued](#) draft guidance on nonclinical testing of individualized antisense oligonucleotide (ASO) drug products for severely debilitating or life-threatening diseases. [Details](#).
- **June 28:** CMS released the FY 2022 IPPS and LTCH PPS [proposed rule](#). [Details](#).
- **June 30:** CMS [announced](#) its annual Call for Measures for the 2021 Medicare Promoting Interoperability Program. [Details](#).
- **July 4:** OMB [issued](#) an RFI seeking feedback on effective methods for determining whether federal agency policies equitably serve all eligible individuals and communities. [Details](#).
- **July 8:** HRSA [announced](#) that it is accepting applications for the FY 2021 Regional Pediatric Pandemic Network (RPPN). [Details](#).
- **July 12:** CMS released an [interim final rule \(IFR\) with comment period](#) that revises infection control requirements related to COVID-19 for long-term and intermediate care facilities. [Details](#).
- **July 15:** HRSA [announced](#) that it is accepting applications for the FY 2022 Children's Hospital Graduate Medical Education (CHGME) Payment Program. [Details](#).

- **July 19:** The FDA [issued](#) draft guidance on feasibility and early feasibility clinical studies for medical devices intended to improve glycemic control in patients with Type 2 diabetes mellitus (T2DM). [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](#).

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