

**Wynne Health Group Weekly**



**FRAMING THE WEEK**

Infrastructure

President Joe Biden will meet with Sen. Shelley Moore Capito (R-WV) on Wednesday, June 3, to continue their negotiations over an elusive **infrastructure package**. While the Biden Administration is encouraged by Senate Republicans' latest infrastructure proposal, the window for reaching a deal appears to be closing. Over the weekend, Transportation Secretary Pete Buttigieg [said](#) that "clear direction" on how to advance infrastructure legislation is needed by the time Congress returns from recess on **June 7**.

The two sides have moved closer to an agreement on a price tag, but they remain far apart on scope and pay-fors. The "clear direction" sought by Secretary Buttigieg may mean indications from Senate Republicans that they will provide some concessions on how to pay for infrastructure investments, which has been the primary sticking point throughout discussions with the White House. However, raising taxes and undoing other Republican tax reforms from 2017 is a "red line" for Senate Minority Leader Mitch McConnell (R-KY). Still, the Administration's efforts to negotiate in earnest with Senate Republicans, while seemingly fruitless, are critical for securing support from moderate Senate Democrats – particularly Sen. Joe Manchin (R-WV), who has pushed for bipartisanship. The Democratic caucus will need to stick together to advance infrastructure legislation through budget reconciliation, their fallback option.

	White House		Senate Republicans	
	March 31	May 21	April 23	May 27
Price Tag	<a href="#">\$2.25 trillion</a>	<a href="#">\$1.7 trillion</a>	<a href="#">\$568 billion</a>	<a href="#">\$928 billion</a>
Scope	Traditional infrastructure and nontraditional infrastructure (including home health, housing, schools, research and development, manufacturing) in <a href="#">American Jobs Plan</a>		Traditional infrastructure only	
Pay-Fors	Increase corporate tax rate to 28 percent (up from 21 percent), other tax reforms		Implement user fees (e.g., electric vehicles), repurpose appropriated federal funds (e.g., coronavirus relief)	

With the [President's fiscal year \(FY\) 2022 budget request](#), House and Senate Budget Committees will begin preparing the FY 2022 budget resolution, which sets overall spending levels and provides instructions for budget reconciliation. The nearly \$6 trillion budget request includes Biden's \$2.3 trillion American Jobs Plan (WHG [client summary](#)), his \$1.8 trillion American Families Plan (WHG [client summary](#)), and \$1.5 trillion in discretionary spending.

Regulatory Update

Having moved into June, we can expect to see the **proposed calendar year (CY) 2022 Medicare payment updates** as early as by the end of the month. These include the Hospital Outpatient Prospective Payment System (HOPPS), Medicare Physician Fee Schedule (MPFS), and the End-Stage Renal Disease Prospective Payment System, among others. A majority of the proposed CY 2022 payment updates are currently pending review at the Office of Management and Budget (OMB) (see [here](#)).

In addition, OMB is now [reviewing](#) a proposed rule entitled, “**Patient Protection and Affordable Care Act; Updating Payment Parameters and Improving Health Insurance Markets for 2022 and Beyond Proposed Rule** (CMS-9906).” Though no formal detail is included on the proposed rule’s contents, the Centers for Medicare & Medicaid Administration (CMS) noted in “[Part 2](#)” of the final CY 2022 Notice of Benefit and Payment Parameters that it would be pursuing additional rulemaking this year to propose new QHP issuer user fee rates (higher than those finalized by the Trump Administration). Notably, CMS also hinted it intends to “revisit” Trump-era proposals – which CMS ultimately did not finalize – that would have authorized states to use private sector entities for enrollment in lieu of centralized Exchange website, as well as regulations governing State Innovation Waivers (i.e., 1332 waivers).

## THIS WEEK IN HEALTH POLICY

### Wed. (6/2)

- **2:00pm-3:00pm – Brookings Webinar: Broadband** – The Brookings Institution hosts a webinar titled, “Can Biden’s broadband infrastructure plan close the digital divide?” [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 117<sup>th</sup> 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

### Fri. (5/28)

- **HHS** released its fiscal year (FY) [2022 Budget in Brief](#) describing major health proposals within the Presidents’ [FY 2022 Budget Request](#). [Details](#).

### Tues. (5/25)

- **The Senate HELP Committee** [convened](#) a markup to examine bipartisan maternal health legislation and other health related bills. [Details](#).

### Wed. (5/26)

- **The House Appropriations Subcommittee** on the Departments of Labor, HHS, Education, and Related Agencies convened a [hearing](#) to examine the FY 2022 budget request for the CDC. [Details](#).
- **HELP Chair Murray (D-WA) and E&C Chairman Pallone (D-NJ)** [announced](#) their plans to develop legislation to establish a federally administered public option. [Details](#).

## REGULATORY LOOKBACK

### Fri. (5/28)

- **The FDA** issued draft guidance on [postmarket surveillance](#) and [post-approval studies imposed by premarket approval](#). [Details](#).

### Thurs. (5/27)

- **CMS** [released](#) the ESRD Treatment Choices (ETC) Model Measurement Year 2 (MY2) achievement benchmarks. [Details](#).
- **CMS** [announced](#) it is encouraging employers of gig workers to share information about their ability to enroll in Marketplace coverage during the 2021 Coronavirus-related SEP. [Details](#).
- **HHS** [announced](#) that \$4.8 billion from the American Rescue Plan (ARP) will be used for the [COVID-19 Uninsured Program](#). [Details](#).

#### **Wed. (5/26)**

- **CMS** [released](#) a proposed rule delaying certain changes made under the Trump Administration for Medicaid value-based arrangements with drug manufacturers. [Details](#).
- **ASPE Office of Health Policy** released a RAND [report](#) about the development of health equity measures. [Details](#).
- **HRSA** [announced](#) it is requesting nominations for qualified individuals to serve as members of the Advisory Committee on Organ Transplantation (ACOT). [Details](#).
- **USPSTF** [issued](#) a final recommendation statement in favor of offering pregnant persons effective behavioral counseling interventions aimed at promoting healthy weight gain. [Details](#).

#### **Tues. (5/25)**

- **HHS** [announced](#) that \$14.2 million in funding available to expand access to pediatric mental health care. Applications are due July 6. [Details](#).

#### **Mon. (5/24)**

- **The FDA** [issued](#) final guidance on bispecific antibody development programs. [Details](#).
- **The FDA** [issued](#) final guidance regarding FDA Reauthorization Act of 2017 (FDARA) implementation for pediatric studies of molecularly targeted oncology drugs. [Details](#).

#### **COMMENT & APPLICATION DEADLINES**

- **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 6:** HHS [announced](#) that \$14.2 million in funding available to expand access to pediatric mental health care. [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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