

**Wynne Health Group Weekly**



**FRAMING THE WEEK**

Infrastructure

Negotiations over the **infrastructure package** continue to intensify this week as President Joe Biden seeks a bipartisan deal, ideally by the end of the month. While Biden and Republican lawmakers expressed optimism after their meeting last week, they remain far apart on fundamental issues – price tag, scope, and most crucially, pay-fors. Senate Minority Leader Mitch McConnell (R-KY) and Sen. Shelley Capito (R-WV), Republicans’ lead negotiator, have reiterated Republicans’ unwillingness to undo their 2017 tax cuts, further complicating the challenge of striking a compromise that satisfies both parties. The White House is expecting a revised counterproposal from Senate Republicans by tomorrow, [according](#) to White House Press Secretary Jen Psaki.

	<b>Biden’s <a href="#">American Jobs Plan</a></b>	<b>Senate Republicans’ <a href="#">Counterproposal</a></b>
<b>Price Tag</b>	\$2.2 trillion	Initially \$568 billion, possibly up to \$800 billion
<b>Scope</b>	\$900 billion traditional infrastructure  \$1.3 trillion nontraditional infrastructure (including home health, housing, schools, research and development, manufacturing)	Traditional infrastructure only
<b>Pay-Fors</b>	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

Absent an agreement, Democrats will likely pursue budget reconciliation to advance infrastructure legislation, including the \$1.8 trillion [American Families Plan](#), over the summer. Executing this legislative maneuver will be no easy feat for Democrats. Hurdles include competing policy priorities within the caucus (e.g., drug price negotiation vs. moderate drug pricing reforms), slim majorities, and of course, the Byrd Rule’s requirements (e.g., significantly affect federal spending or revenue).

Votes This Week

This week, the Senate is slated to begin floor consideration of the **Endless Frontier Act (S. 1260)** – a bill aimed to increase the United States’ technological competitiveness in “key technology focus areas,” through investing in and expanding the National Science Foundation (NSF) and the National Institutes of Standards and Technology (NIST). The initial list of focus areas includes **biotechnology, medical technology, genomics, and synthetic biology**, among other topics. The Senate Committee on Commerce, Science, and Transportation [approved](#) the bill by a vote of 24-4 last week.

The House is slated to consider a [slew of bills](#) throughout the week on a range of issues – including veteran health; science, technology, engineering, and math (STEM) research support; housing; and hate crimes and violence against Asian-Americans and Pacific Islanders; among other topics. On Thursday, the House is expected to pass the **Fairness in Orphan Drug Exclusivity Act (H.R. 1629)** – a bill that would require

manufacturers seeking orphan status for any drug to show they have no reasonable expectation of recovering research and development costs through sales in the U.S. for the entirety of the seven-year exclusivity period.

### Health Care-Focused Hearings

On Wednesday, Sen. Amy Klobuchar (D-MN), who chairs the Senate Judiciary Subcommittee on Competition Policy, Antitrust, and Consumer Rights, will convene a [hearing](#) on **hospital consolidation**. Sen. Klobuchar has introduced [several bills](#) this Congress aimed at curbing anticompetitive behavior – including legislation ([S. 225](#)) that would increase antitrust enforcement and shift the burden from the government to merging companies to prove their merger is legal. Last week, the Senate Judiciary Committee unanimously approved Sen. Klobuchar’s legislation ([S. 228](#)) introduced alongside Sen. Chuck Grassley (R-IA) that would raise merger filing fees to increase the budget for antitrust enforcement.

The Senate Finance Committee will hear from the Government Accountability Office (GAO) and physician stakeholders on Wednesday about “**COVID-19 health care flexibilities**.” The discussion will likely focus on next steps for [coronavirus waivers and flexibilities](#), including telehealth flexibilities, issued by the Centers for Medicare and Medicaid Services (CMS) for after the public health emergency (PHE). The current PHE declaration ends July 20, 2021 and is likely to be in place for the entirety of 2021, according to a [White House letter](#) to governors in January.

On Thursday, the Senate Health, Education, Labor and Pensions Subcommittee on Primary Health and Retirement Security will [examine](#) the **health care workforce shortage**. The hearing will likely inform [forthcoming bipartisan legislation](#) from Chair Patty Murray (D-WA) and Ranking Member Richard Burr (R-NC) aimed at improving nation’s public health infrastructure and medical preparedness and response programs and capabilities.

### Regulatory Update

Last week, the Office of Management and Budget (OMB) [cleared](#) its review of a new proposed rule titled, “**Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value Based Payments (VBP) for Drugs Covered in Medicaid**.” The proposed rule under review shares the same RIN number as the final rule on Medicaid VBP arrangements issued in December 2020 (our full summary [here](#) and attached), suggesting the forthcoming proposed rule could possibly rescind, revise, or otherwise add on to the provisions finalized last year. Its publication in the *Federal Register* is expected shortly.

As a reminder, the December 2020 final rule included provisions allowing state Medicaid programs to enter into VBP arrangements with prescription drug manufacturers, as well as revisions to the best price and average manufacturer price (AMP) exclusions of manufacturer-sponsored patient assistance programs, among other changes.

## **THIS WEEK IN HEALTH POLICY**

### **Tue. (5/18)**

- **10:00am – Hearing: Infrastructure** – The Senate Finance Committee convenes a hearing titled, “Funding and Financing Options to Bolster American Infrastructure.” [Details](#).
- **10:00am – Hearing: Paid Leave** – The Senate, Health, Education, Labor and Pensions Committee convenes a hearing titled, “Paid Leave for Working Families: Examining Access, Options, and Impacts.” [Details](#).
- **10:00am – Hearing: Drug Prices** – The House Oversight Committee convenes a hearing titled, “Unsustainable Drug Prices (Part III): Testimony from AbbVie CEO Richard Gonzalez.” [Details](#).
- **10:30am – Hearing: Broadband** – The House Appropriations Subcommittee on Financial Services and General Government convenes a hearing titled, “The Need for Universal Broadband: Lessons from the COVID-19 Pandemic.” [Details](#).

### Wed. (5/19)

- **10:00am – Hearing: COVID-19** – The Senate Finance Committee convenes a hearing titled, “COVID-19 Health Care Flexibilities: Perspectives, Experiences, and Lessons Learned.” [Details.](#)
- **10:00am – Hearing: CDC Budget** – The Senate Appropriations Subcommittee on Labor, HHS, Education convenes a hearing titled, “Review of the FY2022 Budget Blueprint for the Centers for Disease Control and Prevention.” [Details.](#)
- **10:00am – Hearing: Housing and Assistance** – The Senate Appropriations Subcommittee on Transportation, Housing and Urban Development convenes a hearing titled, “Rethinking Disaster Recovery and Resiliency, Part 2: Protecting Communities and Accelerating Assistance.” [Details.](#)
- **10:00am – Hearing: Tax Reform** – The House Ways and Committee convenes a hearing titled, “Leveraging the Tax Code for Infrastructure Investment.” [Details.](#)
- **10:15am – Hearing: Housing** – The House Education and Labor Subcommittee on Early Childhood, Elementary, and Secondary Education convenes a hearing titled, “Picking up the Pieces: Strengthening Connections with Students Experiencing Homelessness and Children in Foster Care.” [Details.](#)
- **2:00pm – Hearing: Tax Reform** – The Senate Appropriations Subcommittee on Financial Services and General Government convenes a hearing titled, “Internal Revenue Service: Narrowing the Tax Gap and Improving Taxpayer Services.” [Details.](#)
- **2:30pm – Hearing: Hospital Consolidation** – The Senate Judiciary Subcommittee on Competition Policy, Antitrust, and Consumer Rights convenes a hearing titled, “Antitrust Applied: Hospital Consolidation Concerns and Solutions.” [Details.](#)
- **2:30pm – Hearing: COVID-19** – The Senate Homeland Security and Governmental Affairs Committee convenes a hearing titled, “COVID-19 Part II: Evaluating the Medical Supply Chain and Pandemic Response Gaps.” [Details.](#)

### Thurs. (5/20)

- **9:30am – Hearing: Alzheimer’s Disease** – The Senate Special Committee on Aging convenes a hearing titled, “Taking Aim at Alzheimer’s: Frontline Perspectives and Caregiver Challenges.” [Details.](#)
- **10:00am – Hearing: Health Care Workforce** – The Senate Health, Education, Labor and Pensions Subcommittee on Primary Health and Retirement Security convenes a hearing titled, “A Dire Shortage and Getting Worse: Solving the Crisis in the Health Care Workforce.” [Details.](#)

### **FEATURED WHG ANALYSIS**

- **\*NEW\* 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. (5/14)

- In a [letter](#), Reps. Pascrell (D-NJ), Pocan (D-WI), Porter (D-CA), and Doggett (D-TX) ask CMMI to immediately freeze the Direct Contracting Models. [Details](#)

#### Weds. (5/12)

- **The House E&C Subcommittee on Health** [convened](#) a hearing to question HHS Secretary Xavier Becerra about the Biden Administration's FY 2022 discretionary funding request for HHS. [Details.](#)

#### **Tues. (5/11)**

- **The Senate HELP Committee** [convened](#) a hearing to examine the latest efforts to combat COVID-19, including increasing vaccinations and addressing emerging variants. [Details.](#)

#### **REGULATORY LOOKBACK**

#### **Fri. (5/14)**

- **The FDA** issued several guidance documents prepared by the International Council for Harmonisation. [Details.](#)
- **CMS** [announced](#) the further delay of the Medicare Coverage of Innovative Technology (MCIT) final rule effective date until December 21, 2021. [Details.](#)

#### **Thurs. (5/13)**

- **CMS** [released](#) a letter to state Medicaid Directors providing guidance to states on implementing the funding provisions in the ARP for HCBS. [Details.](#)

#### **Tues. (5/11)**

- **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. Comments are due July 12. [Details.](#)
- **CMS** [announced](#) it is seeking nominations for the Advisory Panel on Outreach and Education (APOE). Nominations are due June 11. [Details.](#)
- **AHRQ** [announced](#) it is seeking nominations for members to serve on an initial review group (IRG) for scientific peer review of AHRQ grant applications. Nominations are due June 1. [Details.](#)

#### **Mon. (5/10)**

- **The Treasury Department** launched the [Coronavirus State and Local Fiscal Recovery Funds](#) to provide \$350 billion in emergency funding for state, local, territorial, and Tribal governments. [Details.](#)
- **HHS** [announced](#) it will reverse previous Trump Administration policy on enforcement of sex-based discrimination protections included in the Affordable Care Act. [Details.](#)
- **HHS OIG** released an [issue brief](#) describing efforts by CMS to monitor the use of antipsychotic medications in nursing homes. [Details.](#)
- **CMS** released [guidance](#) for state survey agency directors on hospital admission, discharge, and transfer notification requirements included in its final rule on interoperability and patient access. [Details.](#)
- **CMS** [announced](#) it is seeking nominations for a TEP that will support the development and refinement of PAC quality measures addressing function. Nominations are due May 28. [Details.](#)

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

- **May 21:** Practice application deadline for the [Primary Care First Model](#). [Details.](#)
- **May 21:** CMS [announced](#) the nomination period is now open for Wave 4 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) clinician expert workgroups. [Details.](#)
- **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 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.](#)
- **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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