

Wynne Health Group Weekly



FRAMING THE WEEK

Infrastructure

The “two-track” strategy for infrastructure will continue to take shape this week. The Senate will transform the \$973 billion [bipartisan framework](#) for traditional infrastructure endorsed by President Biden into legislation. The House will take up Democrats’ [INVEST in America Act \(H.R. 3684\)](#), a \$715 billion package that would reauthorize surface transportation programs expiring September 30 and provide funding for other transportation and drinking water infrastructure needs. Given the bipartisan deal on infrastructure in the Senate, this House vote may ultimately be symbolic and will serve as a marker for negotiations with the Senate.

Track 1: Bipartisan Traditional Infrastructure

	Biden-Endorsed Bipartisan Infrastructure Framework	House Democrats’ INVEST in America Act (H.R. 3684) (likely dead on arrival in Senate)
Price Tag (over 5 years)	\$973 billion	\$715 billion
Key Components	Transportation, water, and broadband	Transportation and water

Meanwhile, the budget reconciliation package focused on “human infrastructure” is underway, with lawmakers pushing for various health care reforms. The exact sequencing of the two packages – e.g., bipartisan package followed by budget reconciliation package, or vice versa – remains to be seen.

Track 2: Potential Components of Democrats’ Budget Reconciliation Package (Human Infrastructure & Health Care)

American Jobs Plan (proposals excluded from bipartisan framework)	<ul style="list-style-type: none"> • \$400 billion for home and community-based services • \$180 billion for research and development • \$300 billion for manufacturing • \$30 billion for medical countermeasures manufacturing, research and development, and related biopreparedness and biosecurity • \$100 billion for workforce development • \$213 billion for affordable housing
American Families Plan (\$1.8 trillion)	<ul style="list-style-type: none"> • \$200 billion to make permanent the temporary increase in ACA premium tax credits • \$45 billion for nutrition • \$225 billion for child care • \$225 billion for paid leave • \$506 billion for education
Drug Pricing Reform	<ul style="list-style-type: none"> • H.R. 3 and/or Senate Finance Committee Chairman Ron Wyden (D-OR)’s principles for drug pricing reforms, including:

	<ul style="list-style-type: none"> ○ HHS negotiation (Medicare and/or commercial market) ○ Medicare Part D redesign ○ Inflation rebates for Medicare Part B and Part D drugs ○ Rebate reform
Medicare Expansion	<ul style="list-style-type: none"> ● Add hearing, dental, and vision benefits to traditional Medicare ● Lower the age of Medicare eligibility to 60
Medicaid Gap Coverage	<ul style="list-style-type: none"> ● COVER Now Act would allow counties in states that have not expanded Medicaid to establish demonstration projects to expand Medicaid ● Other financial incentives to persuade holdout states to expand Medicaid ● Federal public option

FY 2022 Appropriations: USDA, FDA

On Wednesday, the House Appropriations Committee is scheduled to mark up the fiscal year (FY) 2022 Agriculture-Rural Development-Food and Drug Administration (FDA) funding bill, which was [approved](#) by the Appropriations Subcommittee last Friday by a voice vote. The \$26.55 billion appropriations legislation billion (a 10 percent increase above FY 2021), which also includes “community project funding” (i.e., earmarks) provides:

- **Nutrition Assistance** – Nearly \$106 billion for the Supplemental Nutrition Assistance Program (SNAP); \$6 billion for Women, Infants, and Children (WIC), \$26.9 billion for various child nutrition programs, and \$45 million for the Summer EBT program.
- **FDA** – Roughly \$3.5 billion for the agency, including \$72 million to address the opioid crisis, medical supply chain surveillance, rare cancers, and inspections; and \$50 million to accelerate medical product development pursuant to the 21st Century Cures Act.
- **Broadband** – \$165 million for rural broadband.

Regulatory Update

On the Medicare payment front, the first of the calendar year (CY) proposed payment updates cleared the Office of Management and Budget (OMB) last week – the [CY 2022 Home Health Prospective Payment System](#). The proposed rule to update payment parameters for the Affordable Care Act (ACA) marketplaces also [cleared](#) OMB review. Both may be released imminently.

THIS WEEK IN HEALTH POLICY

Wed. (6/30)

- **TBD – Markup – FY 2022 Appropriations** – The House Appropriations Committee convenes a markup of the FY 2022 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies appropriations bill. [Details.](#)
- **10:00am – Hearing: Infrastructure** – The House Oversight and Reform Subcommittee on Government Operations convenes a hearing titled, “Catalyst for Change: State and Local IT After the Pandemic.” [Details.](#)
- **10:30am – Hearing: Broadband** – The House Energy and Commerce Subcommittee on Communications and Technology convenes a legislative hearing titled, “A Safe Wireless Future: Securing our Networks and Supply Chains.” [Details.](#)

FEATURED WHG ANALYSIS

- **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](#).
- **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](#).

CONGRESSIONAL LOOKBACK

Thursday (6/24)

- **The House E&C Subcommittee on Health** convened a [hearing](#) to discuss 13 bills aimed at promoting health equity and improving health outcomes. [Details](#).

Wednesday (6/23)

- **Reps. DeGette (D-CO) and Upon (R-MI)** [unveiled](#) the [discussion draft](#) of Cures 2.0 – a bipartisan bill that would authorize the creation of the Advanced Research Projects Agency for Health (ARPA-H). [Details](#).

Tuesday (6/22)

- **Senate HELP Committee** [convened](#) a hearing to discuss vaccination efforts for COVID-19. [Details](#).

REGULATORY LOOKBACK

Friday (6/25)

- **The FDA** updated the [Purple Book: Database of Licensed Biological Products](#) to include the publication of patent lists provided by reference product sponsors for certain biological products. [Details](#).

Thursday (6/24)

- **CMS** [announced](#) it is seeking nominations for a clinician expert workgroup to support the development of chronic kidney disease (CKD) and end-stage renal disease (ESRD) episode-based cost measures. Nominations are due July 16. [Details](#).
- **The FDA** [issued](#) draft guidance entitled “Cancer Clinical Trial Eligibility Criteria: Approach to Available Therapy in Non-Curative Settings.” Comments are due August 27. [Details](#).

Wednesday (6/23)

- **HHS OIG** released a [report](#) about the effects of COVID-19 on nursing home residents covered by Medicare during 2020. [Details](#).
- **Reps. DeGette (D-CO) and Upon (R-MI)** [unveiled](#) the [discussion draft](#) of Cures 2.0 – a bipartisan bill that would authorize the creation of the Advanced Research Projects Agency for Health (ARPA-H). [Details](#).

Tuesday (6/22)

- **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. Comments are due Aug. 27. [Details](#).

Monday (6/21)

- **HHS** [issued](#) a request for information (RFI) on implementing the prescription drug reporting requirements for group health plans and health insurance issuers. Comments are due July 23. [Details](#).

COMMENT & APPLICATION DEADLINES

- **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 16:** HHS [issued](#) a NPRM to rescind the [final rule](#) that implements the President Trump's executive order on access to affordable life-saving medications (penny pricing rule). [Details](#).
- **July 16:** CMS [announced](#) it is seeking nominations for a clinician expert workgroup to support the development of chronic kidney disease (CKD) and end-stage renal disease (ESRD) episode-based cost measures. [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](#).
- **July 23:** HHS [issued](#) a request for information (RFI) on implementing the prescription drug reporting requirements for group health plans and health insurance issuers. [Details](#).
- **August 2:** FDA [issued](#) draft guidance on oral drug products administered via enteral feeding tube. Comments are due August 2. [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](#).
- **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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