

Wynne Health Group Weekly



FRAMING THE WEEK

Congress is in recess this week and returns next Monday, July 12, after which a busy three weeks will follow for lawmakers to work on infrastructure, budget reconciliation, and fiscal year (FY) 2022 appropriations. A brief recap on where things stand with these three legislative priorities follows.

Traditional Infrastructure

The House passed Democrats' [INVEST in America Act \(H.R. 3684\)](#) last week, a \$715 billion package that would reauthorize surface transportation programs expiring September 30 and provide funding for other transportation and drinking water infrastructure needs. The bill is likely to serve as a marker for negotiations with the Senate bipartisan group and the White House, who [recently arrived](#) at their own bipartisan framework for a traditional infrastructure package.

Budget Reconciliation

In the meantime, congressional Democrats are expected to begin work on the second track of its overall infrastructure push, which will contain President Biden's "human infrastructure" proposals reflected in the American Jobs Plan and American Families Plan. Such a package would need to move through budget reconciliation and could therefore contain a number of other Democratic priorities, including drug pricing reform; expanding the Medicare benefit to include dental, vision, and hearing; and Medicaid gap coverage.

How exactly Democrats will proceed will depend on the forthcoming FY 2022 budget resolution. House Democrats recently signaled they will await the Senate's budget resolution and forgo developing their own in the meantime. The House may likely end up adopting the Senate budget resolution and is hoping to have a final, adopted budget resolution before the August recess.

FY 2022 Appropriations

Upon return from recess, the House Appropriations Committee will [resume markups](#) of FY 2022 appropriations bills. The subcommittee markup for the Labor-HHS-Education bill is scheduled for July 12, with a full committee markup scheduled thereafter for July 15. Last week, the House Appropriations Committee [approved](#) the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies (Agriculture-FDA) appropriations bill, as well as [allocations](#) known as 302(b)s for its 12 subcommittees for FY 2022, which includes Labor-HHS-Education and will provide in total more than \$1.5 trillion in funding.

Regulatory Update

Last week, CMS kicked off its calendar year (CY) 2022 Medicare payment update cycle with the release of two proposed regulations: the CY 2022 end-stage renal disease (ESRD) prospective payment system (PPS) and the Home Health PPS (WHG summaries [here](#) and [here](#)). The other major CY 2022 payment updates – the Medicare Physician Fee Schedule, Hospital Outpatient PPS – remain under review at the

Office of Management and Budget (OMB) but could be released in the near term. Both were slated for release in June per the [most recent Unified Agenda](#).

THIS WEEK IN HEALTH POLICY

Mon. (7/5)

WHG is closed in observance of Independence Day. Congress is in recess through Friday, July 9.

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

Wednesday (6/30)

- **The House Appropriations Committee** [convened a markup](#) of the fiscal year (FY) 2022 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies [appropriations bill](#). [Details](#).

REGULATORY LOOKBACK

Thursday (7/1)

- **CMS** released the CY 2022 end-stage renal disease (ESRD) prospective payment system (PPS) proposed rule. [Details](#).
- **Departments** released an interim final rule with comment (IFC) that implements the first set of requirements related to surprise billing. [Details](#).
- **ASPE** released an [issue brief](#) examining the American Rescue Plan's (ARP) provisions to make health coverage more affordable for people receiving unemployment compensation. [Details](#).

Wednesday (6/30)

- **CMS** [released](#) an updated data snapshot detailing the impact of COVID-19 on Medicare beneficiaries. [Details](#).
- **HHS** [announced](#) new lower-cost options for consumers through the ACA Exchanges. [Details](#).
- **The NIH** Office of Research on Women's Health [requests](#) comments to inform planning of the Women's Health Consensus Conference. Comments are due September 15. [Details](#).

Tuesday (6/29)

- **HHS OIG** [performed](#) an audit to determine whether CMS designed and implemented effective internal controls related to hospital preparedness for emerging infectious diseases. [Details](#).
- **USDA** [released](#) a study on the barriers that SNAP participants face to achieving a healthy diet. [Details](#).

Monday (6/28)

- **CMS** [released](#) a proposed rule to improve access and affordability for consumers in the individual market. Comments are due July 28. [Details](#).

- **CMS issued** the cycle year (CY) 2022 home health prospective payment system and rate update proposed rule. Comments are due August 27. [Details](#).
- **CMS released** 2021 Alternative Payment Model (APM) Incentive Payment details on the Quality Payment Program (QPP) [website](#). [Details](#).
- **ASPE** released an [issue brief](#) detailing findings on COVID-19 related trends in Medicare Fee-For-Service (FFS) beneficiary utilization and provider payments during 2020. [Details](#).

COMMENT & APPLICATION DEADLINES

- **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](#).
- **July 28:** CMS [released](#) a proposed rule to improve access and affordability for consumers in the individual market. [Details](#).
- **August 2:** FDA [issued](#) draft guidance on oral drug products administered via enteral feeding tube. Comments are due August 2. [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](#).
- **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](#).

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