Wynne Health Group Weekly

FRAMING THE WEEK

The trifecta of legislative priorities – **traditional infrastructure, budget reconciliation** (a catchall for human infrastructure and health care items), and **fiscal year (FY) 2022 appropriations** – continues to take shape this week. As the group of bipartisan senators transform their framework for nearly $1 trillion for traditional infrastructure into legislation, Senate Democrats are crafting the FY 2022 budget resolution that will include instructions for budget reconciliation. Senate Majority Leader Chuck Schumer (D-NY) is pushing for Congress to pass the traditional infrastructure package and FY 2022 budget resolution before the summer recess (August 2 for the House and August 9 for the Senate). The House could then vote on these measures when they return in September.

Today, the **House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies** will mark up its FY 2022 spending bill. The full committee markup is slated for Thursday, July 15. The bill provides $119.8 billion to HHS, $22.9 billion above the FY 2021 enacted level, and includes increases for the Centers for Disease Control and Prevention (CDC) and the National Institutes for Health (NIH). House Democrats dropped the Hyde Amendment, the longstanding ban on federal funding for most abortions, though it may ultimately be included in the spending bill given the tight margins in the House and Senate. The spending bill also funds the **Advanced Research Projects Agency for Health (ARPA-H)**, the agency within the NIH envisioned by the Biden Administration to accelerate transformation innovation in health research. The bipartisan discussion draft for Cures 2.0 from Reps. Diana DeGette (D-CO) and Fred Upton (R-MI) would authorize the establishment of ARPA-H.

Regulatory Update

The proposed **calendar year (CY) 2022 Medicare Physician Fee Schedule** cleared review at the White House Office of Management and Budget (OMB) last Friday. Its release is now expected imminently. In addition to the annual payment updates for physician services, the proposed rule may include additional COVID-related telehealth updates as well as additional requests for information on how CMS can better address health equity issues through its payment programs.

Beyond this, a number of regulations arrived at OMB last week for review. Most notable among these is a proposed rule pending review regarding CMS's **Most Favored Nation's (MFN) model**. As a reminder, the final rule as released by the Trump Administration is currently on hold due to multiple court preliminary injunctions that cite the Administration's failure to complete notice and comment procedures. The new rule could either withdraw the previous rule or the Biden Administration could propose its own MFN model. OMB is also reviewing a proposed rule regarding **reporting requirements for air ambulances** (here) as well as the **fiscal year (FY) 2022 Inpatient Psychiatric Facilities Prospective Payment System final rule** (here).

THIS WEEK IN HEALTH POLICY

Mon. (7/12)
- **11:00am – Markup: FY 2022 Appropriations** – The House Appropriations convenes a subcommittee markup of the FY 2022 Labor, Health, and Human Services, Education, and Related Agencies appropriations bill. Details.

- **12:00pm – Hearing: SNAP** – The House Agriculture Committee, Subcommittee on Nutrition, Oversight and Department Operations, convenes a hearing titled, "Examining the SNAP Benefit Cliff." Details.

Tue. (7/13)
- **12:00pm – FDA Webinar: PPE** – The Food and Drug Administration is holding a webinar titled, "Respirators and Other Personal Protective Equipment (PPE) for Health Care Personnel Use During the COVID-19 Pandemic." Details.
- **2:30pm – Hearing: Prescription Drugs** – The Senate Committee on the Judiciary, Subcommittee on Competition Policy, Antitrust, and Consumer Rights convenes a hearing titled, "A Prescription for Change: Cracking Down on Anticompetitive Conduct in Prescription Drug Markets." Details.

Wed. (7/14)
- **9:30am – ONC Meeting: Health IT** – The Office of the National Coordinator for Health Information Technology (ONC) convenes a meeting of the Health IT Advisory committee. Details.

Thurs. (7/15)
- **TBA – Markup: FY 2022 Appropriations** – The House Appropriations Committee convenes a markup of the FY 2022 Commerce, Justice, Science and Related Agencies appropriation bill, and the FY 2022 Labor, Health, and Human Services, Education, and Related Agencies appropriations bill. Details.

Additional Multi-Day Events
- **7/21 1:00pm and 7/23 9:00am – Public Workshop: FDA** – The Food and Drug Administration convenes the 6th Annual Clinical Outcome Assessment in Cancer Clinical Trials Workshop. Details.

FEATURED WHG ANALYSIS

- *NEW* **WHG Updated 2021 Legislative and Regulatory Outlook** – In the Policy Hub Insight Bank here.
- **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.

CONGRESSIONAL LOOKBACK

Thursday (7/8)
- **The House Committee on Oversight and Reform** released a report that examines financial data from the fourteen largest drug companies in the world. Details.

REGULATORY LOOKBACK

Friday (7/9)
- **President Biden** signed an executive order (EO) to promote competition in the U.S. economy. Details here and here.
- **The CDC** seeks nominations for the CDC/Health Resources & Services Administration (HRSA) Advisory Committee on HIV, Viral Hepatitis, and STD Prevention and Treatment (CHACHSPT). Nominations are due August 31. Details.

Thursday (7/8)

- **The White House ONDCP** issued a request for information seeking feedback on whether and to what extent its policies and programs perpetuate systemic barriers to opportunities for underserved communities. Comments are due August 6. Details.
- **The FDA and HHS** announced the withdrawal of the RFPs for insulin reimportation and individual prescription drug importation. Details.

Tuesday (7/6)
- **CMS** is currently accepting comments on the development and maintenance of the outcome electronic clinical quality measure (eCQM), Hospital Harm – Falls with Major Injury. Comments are due July 28. Details.
- **The FDA** issued final guidance on the form and content of the unique device identifier (UDI). Details.
- **The FDA** issued final guidance on evaluating cancer drugs in patients with central nervous system (CNS) metastases.

COMMENT & APPLICATION DEADLINES

- **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.
- **July 28:** CMS is currently accepting comments on the development and maintenance of the outcome electronic clinical quality measure (eCQM), Hospital Harm – Falls with Major Injury. Details.
- **August 2:** FDA issued draft guidance on oral drug products administered via enteral feeding tube. Comments are due August 2. Details.
- **August 6:** The White House ONDCP issued a request for information seeking feedback on whether and to what extent its policies and programs perpetuate systemic barriers to opportunities for underserved communities. 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.
- **August 31:** The CDC seeks nominations for the CDC/Health Resources & Services Administration (HRSA) Advisory Committee on HIV, Viral Hepatitis, and STD Prevention and Treatment (CHACHSPT). 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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