### This Week in Health Policy, Congressional Lookback, Regulatory Lookback, Comment & Application Deadlines

### Wynne Health Group Weekly



#### FRAMING THE WEEK

#### Infrastructure

The White House is ramping up its push for a bipartisan deal on infrastructure. President Joe Biden will meet with **Democratic and Republican leadership** from the House and Senate on Wednesday and top Republican committee leaders on Thursday. These meetings are expected to focus on the scope and price tag of Biden's broader infrastructure package (<u>American Jobs Plan</u> and <u>American Families Plan</u>) as well as how to pay for the spending. With both parties far apart on infrastructure, the meetings are crucial for any chances of a bipartisan agreement.

The compromise could be a traditional infrastructure package (i.e., transportation, drinking water, and broadband) totaling \$800 billion – the top of Senate Minority Leader Mitch McConnell's (R-KY) price range and just shy of the \$832 billion investment Biden proposed for those elements. We could then see Democrats push a large, potentially multi-trillion-dollar package – composed of their other priorities in the American Jobs Plan (e.g., home and community-based services, workforce development) and the American Families Plan – through budget reconciliation.

#### COVID-19 Response

Tomorrow, the Senate Health, Education, Labor and Pensions Committee will <u>hear</u> from key members of **Biden's COVID-19 response team**. Questions will likely focus on the Administration's efforts to achieve Biden's latest <u>goal</u> – administer at least one vaccine shot to 70 percent of adults by July 4. According to the <u>Centers for Disease Control and Prevention (CDC)</u>, 58 percent of adults have received at least one dose and roughly 44 percent are fully vaccinated. The Administration's recent <u>actions</u> include distributing <u>\$250</u> million for community-based organizations to support vaccinations in underserved communities and directing pharmacy partners to make no-appointment walk-up vaccinations available.

On Wednesday, CDC's <u>Advisory Committee on Immunization Practices (ACIP)</u> will vote on the use of **Pfizer's COVID-19 vaccine in adolescents aged 12 to 15**. Last Friday, Pfizer <u>submitted</u> its application to expand the current emergency use authorization for their COVID-19 vaccine to include adolescents. The company also began the process for seeking full Food and Drug Administration (FDA) approval for their vaccine.

#### HHS Budget and Personnel

On Wednesday, the House Energy and Commerce Committee will <u>question</u> Xavier Becerra, Secretary of Health and Human Services, about the Department's <u>fiscal year (FY) 2022 discretionary funding request</u>. The Biden Administration requests **\$131.7 billion for HHS**, a 23.5 percent increase over the FY 2021 enacted level. The increase reflects significant funding for public health modernization; research on cancer, Alzheimer's disease, and diabetes; mental health; the opioid epidemic; HIV/AIDS; gun violence; and health

equity-related initiatives such as social determinants and maternal mortality. With Becerra in the hot seat, lawmakers may also ask him about enforcement of the hospital price transparency rule (an issue of <u>keen</u> <u>interest</u> to both parties), implementation of the No Surprises Act, drug price negotiation, the COVID-19 response, and unaccompanied children at the border, among other topics.

The Senate is slated to vote this week on the nomination of **Andrea Joan Palm to be Deputy Secretary** of **Health and Human Services**. A vote has not yet been scheduled for Chiquita Brooks-LaSure, Biden's pick to lead the Centers for Medicare and Medicaid Services, due to objections by Senate Republicans to the Biden Administration's revocation of Texas's Medicaid waiver. Brook-LaSure is still expected to be confirmed.

### House Floor Activity: Mental and Behavioral Health, Orphan Drugs, Controlled Substances

This week, the House will vote on a slew of bills that would authorize various new grant programs aimed at increasing **access to mental and behavioral health services.** The <u>Senate Finance Subcommittee</u> on Health Care and the <u>House Appropriations Subcommittee</u> on Labor, HHS, and Education will also convene hearings this week on policies and programs to bolster the federal government's response to the mental health crisis.

- <u>H.R. 433</u> Family Support Services for Addiction Act of 2021
- <u>H.R. 1475</u> Pursuing Equity in Mental Health Act
- <u>H.R. 586</u> STANDUP Act of 2021
- <u>H.R. 721</u> Mental Health Services for Students Act of 2021
- <u>H.R. 2877</u> Behavioral Intervention Guidelines Act of 2021
- <u>H.R. 1260</u> Bipartisan Solution to Cyclical Violence Act of 2021
- <u>H.R. 1205</u> Improving Mental Health Access from the Emergency Department Act of 2021
- <u>H.R. 1324</u> Effective Suicide Screening and Assessment in the Emergency Department Act of 2021
- <u>H.R. 1480</u> HERO Act
- <u>H.R. 2862</u> Campaign to Prevent Suicide Act
- <u>H.R. 2981</u> Suicide Prevention Lifeline Improvement Act of 2021
- <u>H.R. 2955</u> Suicide Prevention Act

The House will also vote on <u>H.R. 1629</u>, which would modify limitation on exclusive approval or licensure of **orphan drugs**. Additionally, the House will vote on <u>H.R. 768</u>, which would create additional requirements for drug manufacturers and distributors who discover a suspicious order for **controlled substances**.

### THIS WEEK IN HEALTH POLICY

#### Mon. (5/10)

• **5:30pm – Business Meeting: USDA** – The Senate Agriculture, Nutrition, and Forestry Committee convenes a hearing to vote on the nomination of Dr. Jewel H. Bronaugh to be Deputy Secretary of Agriculture. <u>Details</u>.

### Tue. (5/11)

 10:00am – Hearing: COVID-19 – The Senate Health, Education, Labor and Pensions Committee convenes a hearing titled, "An Update from Federal Officials on Efforts to Combat COVID-19." <u>Details</u>.

## Wed. (5/12)

- **10:00am Hearing: Family Support** The House Ways and Means Subcommittee on Worker and Family Support convenes a hearing titled, "Making a Different for Families and Foster Youth." <u>Details</u>.
- **10:00am Hearing: Tax Code** The Senate Joint Economic Committee convenes a hearing titled, "Examining the Racial Wealth Gap in the United States." <u>Details</u>.
- **10:15am Hearing: Nutrition** The House Education and Labor Subcommittee on convenes a hearing titled, "Examining the Policies and Priorities of the U.S. Department of Agriculture's Food and Nutrition Service." <u>Details</u>.
- 10:30am Hearing: HHS Budget The House Energy and Commerce Committee convenes a hearing titled, "The Fiscal Year 2022 HHS Budget." <u>Details</u>.
- **11:00am-5:00pm CDC Meeting: COVID-19 Vaccine** The CDC convenes a meeting of the Advisory Committee on Immunization Practices (ACIP) to discuss the Pfizer COVID-19 vaccine for use among persons aged 12–15 years, among other topics. <u>Details</u>.
- **2:00pm Hearing: Tax Code** The House Ways and Means Subcommittee on Select Revenue Measures convenes a hearing titled, "Reforming the Tax Code's Advantageous Treatment of the Wealthy." <u>Details</u>.
- **3:00pm Hearing: Mental Health** The Senate Finance Subcommittee on Health Care convenes a hearing titled, "The COVID-19 Pandemic and Beyond: Improving Mental Health and Addiction Services in Our Communities." <u>Details</u>.

### Thurs. (5/13)

- 10:00am Hearing Mental Health The House Appropriations Subcommittee on Labor, HHS, Education convenes a hearing titled, "Mental Health Emergencies: Building a Robust Crisis Response System." <u>Details</u>.
- **10:15am Hearing: Workforce** The House Education and Labor Subcommittee on Higher Education and Workforce Investment convenes a hearing titled, "Workforce Innovation and Opportunity Act Reauthorization: Creating Opportunities for Youth Employment." <u>Details</u>.

### FEATURED WHG ANALYSIS

- WHG Chart of the Major Drug Pricing Proposals in the 117<sup>th</sup> Congress In the Policy Hub Insight Bank <u>here</u>.
- 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 <u>here</u>.
- Summary of Recent Federal Actions on Maternal Health & Gender Equity In the Policy Hub Insight Bank <u>here</u>.
- **Prospects for Drug Pricing Reform Under a Biden-Harris Administration** Featured on The Commonwealth Fund's *To the Point* <u>here</u>.
- Support for States' COVID-19 Response Efforts in the American Rescue Plan Featured on The Commonwealth Fund's *To the Point* <u>here</u>.

### **CONGRESSIONAL LOOKBACK**

### **Thurs. (5/6)**

- **The House Oversight Committee** convened a <u>hearing</u> to examine the maternal mortality and morbidity crisis experienced by Black birthing people in America. <u>Details</u>.
- The White House issued a series of individualized fact sheets outlining how the proposed American Families Plan would supporting existing needs specific to each state and U.S. territory. Details.

## <u>Tues. (5/4)</u>

• The House E&C Subcommittee on Health <u>convened</u> a hearing to examine bills related to prescription drugs. <u>Details</u>.

### **REGULATORY LOOKBACK**

# <u>Fri. (5/7)</u>

- **HRSA** <u>announced</u> that it is accepting applications for the FY 2021 Regional Pediatric Pandemic Network (RPPN). Applications are due July 8. <u>Details</u>.
- **HRSA** <u>announced</u> that it is accepting applications for the FY 2022 Children's Hospital Graduate Medical Education (CHGME) Payment Program. Applications are due July 15. <u>Details</u>.

## **Thurs. (5/6)**

- **CMS** <u>increased</u> the national average payment rate for monoclonal antibody treatments in most health care settings from \$310 to \$450. <u>Details</u>.
- **CMS** announced (<u>press release</u>; <u>fact sheet</u>) nearly 940,000 new enrollees have signed up for health insurance plans since the Coronavirus-related SEP opened. <u>Details</u>.
- **CMS** issued a <u>waiver</u> that permits Medicare to pay for ground ambulance services without a transport during the COVID-19 public health emergency. <u>Details</u>.

# Weds. (5/5)

- **CMS** <u>announced</u> its annual Call for Measures for the 2021 Medicare Promoting Interoperability Program. Submissions are due June 30. <u>Details</u>.
- The AHRQ is <u>seeking public comments</u> on clinical algorithms used in medical practice that may introduce bias into decision-making. Responses are due May 11. <u>Details</u>.
- **The AHRQ** <u>issued</u> an FOA for research projects that test promising digital healthcare interventions at the point of care. Applications are due June 16. <u>Details</u>.

### Tues. (5/4)

- **OMB** <u>issued</u> an RFI seeking feedback on effective methods for determining whether federal agency policies equitably serve all eligible individuals and communities. Comments are due July 4. <u>Details</u>.
- **HHS** <u>announced</u> it is making nearly \$1 billion available to support rural communities as they continue their COVID-19 response efforts. <u>Details</u>.
- **HHS** is <u>making available</u> approximately \$250 million to continue its vaccine confidence and uptake strategies in vulnerable communities. <u>Details</u>.

### Mon. (5/3)

• **HHS** launched the <u>COVID-19 Coverage Assistance Fund</u> (CAF) – a new program at HRSA that will reimburse providers for the costs of administering COVID-19 vaccines to underinsured patients. <u>Details</u>.

• The White House announced that the HHS' ACL is releasing \$1.4 billion in funding to support a number of initiatives aimed at older adult health. <u>Details</u>.

## **COMMENT & APPLICATION DEADLINES**

- **May 11:** CMS <u>released</u> a notice of funding opportunity (NOFO) to accompany the ambulance payment component of the Emergency Triage, Treat, and Transport (ET3) Model that began January 1, 2021. <u>Details</u>.
- **May 14:** HHS <u>announced</u> the availability of \$150 million in grant funding to support approximately 100 Health Center Program look-alikes (LALs) to respond to and mitigate the spread of COVID-19. <u>Details</u>.
- May 15: HHS issued a proposed rule to revise the rules that govern the Title X Family Planning Program (fact sheet). Details
- May 21: Practice application deadline for the <u>Primary Care First Model</u>. <u>Details</u>.
- **May 21:** CMS <u>announced</u> the nomination period is now open for Wave 4 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) clinician expert workgroups. <u>Details</u>.
- May 24: The FDA issued draft and revised draft product-specific guidances. Details.
- June 4: USDA <u>announced</u> that it is accepting applications for Distance Learning and Telemedicine (DLT) program grants to help provide educational and medical services in rural areas. <u>Details</u>.
- June 7: CMS <u>released</u> its proposed rule for the fiscal year (FY) 2022 Inpatient Psychiatric Facility (IPF) Prospective Payment System (PPS) (<u>fact sheet</u>). <u>Details</u>.
- June 7: CMS <u>released</u> the fiscal year (FY) 2022 inpatient rehabilitation facility (IRF) prospective payment system (PPS) proposed rule (<u>press release</u>). <u>Details</u>.
- June 7: CMS released its <u>proposed rule</u> for the fiscal year (FY) 2022 Skilled Nursing Facility (SNF) Prospective Payment System (PPS) (<u>fact sheet</u>). <u>Details</u>.
- June 7: CMS released its FY 2022 Hospice Wage Index proposed rule (fact sheet). Details.
- June 11: CMS <u>issued</u> a notice of funding opportunity for its Minority Research Grant Program. <u>Details</u>.
- June 16: The AHRQ <u>issued</u> an FOA for research projects that test promising digital healthcare interventions at the point of care. <u>Details</u>.
- June 18: Payer application deadline for the <u>Primary Care First Model</u>. <u>Details</u>.
- June 26: The FDA <u>issued</u> draft guidance on nonclinical testing of individualized antisense oligonucleotide (ASO) drug products for severely debilitating or life-threatening diseases. <u>Details</u>.
- June 28: CMS released the FY 2022 IPPS and LTCH PPS proposed rule. Details.
- June 30: CMS <u>announced</u> its annual Call for Measures for the 2021 Medicare Promoting Interoperability Program. <u>Details</u>.
- July 4: OMB <u>issued</u> an RFI seeking feedback on effective methods for determining whether federal agency policies equitably serve all eligible individuals and communities. <u>Details</u>.
- July 8: HRSA <u>announced</u> that it is accepting applications for the FY 2021 Regional Pediatric Pandemic Network (RPPN). <u>Details</u>.
- July 15: HRSA <u>announced</u> that it is accepting applications for the FY 2022 Children's Hospital Graduate Medical Education (CHGME) Payment Program. <u>Details</u>.
- **September 17:** The CDC <u>announced</u> it is seeking nominations for individuals to serve as members of the Healthcare Infection Control Practices Advisory Committee. <u>Details</u>.

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