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

Wynne Health Group Weekly



WHG UPDATE

WHG will be closed on Friday, June 18, to commemorate <u>Juneteenth</u>, the end of slavery in the United Sates (on June 19, 1865) and to promote racial justice. As a mission-driven, public-service government relations firm, we are committed to partnering with our clients to further federal policies that eliminate racial and ethnic disparities in health and health care and to practicing anti-racism throughout our work. We welcome the opportunity to talk at any time about how we can work together to combat racism and further racial justice, especially in health and health care. For more information about the WHG's anti-racism commitments, as well as our ongoing Diversity, Equity and Inclusion (DEI) work, please see here and here.

FRAMING THE WEEK

Negotiations over **infrastructure legislation** continue, with a bipartisan group of 10 senators leading the discussions with the White House. Like the Biden Administration's talks with Sen. Shelley Moore Capito (R-WV), the main sticking point is how to pay for infrastructure investments. Whether the new bipartisan proposal, even if supported by the White House, can garner the 60 votes needed to block a filibuster remains to be seen. Meanwhile, Democrats will push forward with the **budget reconciliation process** as an alternative pathway for advancing President Biden's American Jobs Plan and American Families in July.

Today, House Budget Chair John Yarmuth (D-KY) is slated to introduce a "**deeming resolution**," which will provide spending allocations to House appropriators for fiscal year (FY) 2022. The deeming resolution is expected to set discretionary spending at \$1.5 trillion, which aligns with President Biden's FY 2022 budget request. The House Appropriations Committee plans to begin marking up **FY 2022 spending bills** on June 24.

	White House			Bipartisan Group of <u>10 Senators</u>	Senate Republicans (No Deal)	
	March 31	May 21	June 2	June 10	April 23	May 27
Size	<u>\$2.25</u> trillion	\$1.7 trillion		\$1.2 trillion over 8 years (\$974 billion over 5 years)	<u>\$568 billion</u>	<u>\$928 billion</u>
Pay-For	Increase corporate tax rate to 28 percent (up from 21 percent), other tax reforms		No corporate tax increase; increase the global minimum tax rate to 15 percent (up from 10.5 percent) and increase tax enforcement; other tax reforms	No tax increase; other details not specified	Implement us (e.g., electric repurpose ap federal funds coronavirus r	vehicles), ppropriated (e.g.,

Scope	Traditional infrastructure and nontraditional infrastructure (including home health, housing, schools, research and development, manufacturing) in <u>American Jobs Plan</u>	Traditional infrastructure only	Traditional infrastructure only
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HHS Policies, Surprise Medical Billing

Health and Human Services (HHS) Secretary Xavier Becerra will be back on Capitol Hill on Wednesday to answer questions about the Department's policies and priorities, this time before the <u>House Education</u> and Labor Committee. Questions are likely to focus on the FY 2022 budget for HHS as well as the newly released <u>spring 2021 unified agenda</u>, which sets the Biden Administration's regulatory playbook for the coming months.

The unified agenda includes the highly anticipated **implementation of surprise billing legislation** enacted in December 2020. The <u>first interim final rule with comment</u>, with a target date of July 2021, is expected to include components statutorily required to be issued by July 1, 2021. They are:

- Methodology for determining the "qualifying payment amount," which is generally the median contracted rate. The qualifying payment amount is one of the factors that an arbiter will consider when making a payment determination. Insurers will also use the qualifying payment amount to calculate the cost-sharing requirement for items and services that fall within the scope of protections (e.g., emergency services furnished by out-of-network hospitals); and
- **Guidance on notice and consent requirements** for out-of-network providers and facilities. A provider or facility may balance bill a patient for allowable services (e.g., non-emergency services) if they obtain consent within 72 hours before the delivery of care.

The second <u>interim final rule with comment</u>, scheduled for August 2021, is expected to establish the **independent dispute resolution process**, including how arbiters must weigh the multiple factors when considering the payment determination. Policymakers and stakeholders alike will be highly attuned to whether the qualifying payment amount carries more weight than other factors, such as patient acuity or complexity of the item or service. In late April, Sens. Maggie Hassan (D-NH) and Bill Cassidy (R-LA) <u>emphasized</u> to the Administration that the intent of the law is to "give each arbitration factor [including the qualifying payment amount] equal weight and consideration."

Mental and Behavioral Health

Tomorrow, the <u>Senate Finance Committee</u> (SFC) will hold a hearing to discuss policy solutions to increase mental health care access, a pressing need amid the COVID-19 pandemic. Based on the findings of a Government Accountability Office (GAO) report <u>requested</u> by SFC Chairman Ron Wyden (D-OR), the policy solutions discussed may focus on **increasing the behavioral health workforce; increasing oversight of claims payments, particularly in Medicaid; and intensifying enforcement of mental health parity requirements.**

The GAO <u>report</u> found a shortage of qualified behavioral health professionals, particularly in rural areas in its review of federal data. GAO interviewed stakeholders, including the National Council for Behavioral Health and hospital associations and insurance regulators in four states (OR, PA, TX, and VA). Stakeholders cited "concerns about denials or delays in payment for behavioral health services" but "identified limited data to assess the extent of issues with the payment of claims for behavioral health services."

Vaccine-Focused Legislation

Tomorrow, the House Energy and Commerce Subcommittee on Health will convene a hearing to discuss a slew of bills aimed at bolstering the nation's immunization infrastructure and public health system. The Health Subcommittee will address bills centered on the COVID-19 pandemic – e.g., requiring weekly reports to COVID-19 on COVID-19 vaccine distribution, including **disaggregated data on COVID-19 vaccine distribution** (H.R. 979); and requiring HHS to publish the formula used to determine the allocation of COVID-19 vaccines to states, localities, etc. (H.R. 1452). Other bills are broader in scope and seek to strengthen immunization infrastructure (H.R. 550). The slate also includes bills that would revise **vaccine coverage requirements for adults under traditional Medicaid** (H.R. 2170) and modify **eligibility for the Vaccines for Children Program** (H.R. 2347). See the <u>briefing memo</u> for additional details.

THIS WEEK IN HEALTH POLICY

<u>Tue. (6/15)</u>

- 10:00am Hearing: Mental Health The Senate Finance Committee convenes a hearing titled, "Mental Health Care in America: Addressing Root Causes and Identifying Policy Solutions." <u>Details</u>.
- 10:00am Hearing: USDA Budget The Senate Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies convenes a hearing on the FY 2022 budget request for the U.S. Department of Agriculture. <u>Details</u>.
- 10:00am Hearing: Infrastructure The Senate Banking, Housing, and Urban Affairs Committee convenes a hearing titled, "21st Century Communities: Local Leaders on the Infrastructure Needs Facing America's States, Cities, and Towns." <u>Details</u>.
- 10:15am Hearing: Workforce The House Education and Labor Committee convenes a hearing titled, "Workforce Innovation and Opportunity Act Reauthorization: Examining Successful Models of Employment for Justice-Involved Individuals." Details.
- 10:30am Hearing: Vaccines The House Energy and Commerce Subcommittee on Health convenes a hearing titled, "Booster Shot: Enhancing Public Health through Vaccine Legislation." Details.

Wed. (6/16)

- TBD Executive Session: HHS and Labor Nominations The Senate Health, Education, Labor and Pensions Committee convenes an executive session to consider the nominations of assistant secretaries at HHS and Labor. <u>Details</u>.
- 9:00am Hearing: HHS Policies The House Education and Labor Committee convenes a hearing titled, "Examining the Policies and Priorities of the U.S. Department of Health and Human Services," featuring HHS Secretary Xavier Becerra. <u>Details</u>.
- **10:00am Hearing: FY 2022 Budget** The Senate Finance Committee convenes a hearing on the President's FY 2022 budget, featuring Treasury Secretary Janet Yellen. <u>Details</u>.
- **10:00am Hearing: Housing** The House Veterans' Affairs Committee convenes a hearing titled, "Veteran Homelessness in the Wake of COVID-19." <u>Details</u>.
- **3:00pm Hearing: VA Budget** The Senate Veterans' Affairs Committee convenes a hearing titled, "Review of the Fiscal Year 2022 Budget and 2023 Advance Appropriations Requests for the Department of Veterans Affairs." <u>Details</u>.

<u>Thurs. (6/17)</u>

- 9:30am Hearing: Caregivers The Senate Special Committee on Aging convenes a hearing titled, "21st Century Caregiving: Supporting Workers, Family Caregivers, Seniors and People with Disabilities." <u>Details</u>.
- **10:00am Hearing: COVID-19 and Education** The Senate Health, Education, Labor and Pensions Committee convenes a hearing titled, "COVID-19 Response and Recovery: Supporting the Needs of Students in Higher Education & Lessons on Safely Returning to Campus on Safely Returning to Campus." <u>Details</u>.
- 10:00am Hearing: FY 2022 Budget The House Ways and Means Committee convenes a hearing on the President's FY 2022 budget, featuring Treasury Secretary Janet Yellen. <u>Details</u>.

<u>Fri. (6/18)</u>

Observation of Juneteenth

FEATURED WHG ANALYSIS

- *NEW* WHG Chart Key Federal Public Option Bills in the 117th Congress; Side-by-Side Comparison – In the Policy Hub Insight Bank <u>here</u>.
- WHG Overview of Recent Development on Federal Telehealth Policy In the Policy Hub Insight Bank <u>here</u>.
- WHG Chart of the Major Drug Pricing Proposals in the 117th 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>.

CONGRESSIONAL LOOKBACK

<u>6/10</u>

• Senate Finance Committee convened a full committee hearing to examine President Biden's FY 2022 budget for the Department of Health and Human Services (HHS). <u>Details</u>.

<u>6/9</u>

• Senate Appropriations Subcommittee on the Departments of Labor, Health and Human Services (HHS), Education, and Related Agencies convened a hearing to question HHS Secretary Xavier Becerra (testimony) about the fiscal year (FY) 2022 budget request for HHS. <u>Details</u>.

<u>6/8</u>

 House Ways and Means Committee_convened a hearing with Department of Health and Human Services (HHS) Secretary Xavier Becerra to discuss President Biden's FY 2022 budget proposal. Details.

REGULATORY LOOKBACK

<u>6/10</u>

- **CMS** recently released a report that provides a national impact assessment of its quality measures. This report is released every three years. <u>Details</u>.
- **OSHA** issued an emergency temporary standard (ETS) aimed at protecting workers in healthcare settings from COVID-19. <u>Details</u>.

<u>6/9</u>

 CMS announced it will pay an additional \$35 per dose for COVID-19 vaccine administration in a Medicare beneficiary's home. <u>Details</u>.

<u>6/8</u>

• **CMS** released a report outlining guidelines to using the health-related social needs (HRSN) screening tool from the Accountable Health Communities (AHC) Model. <u>Details</u>.

<u>6/7</u>

- **CMS** announced 31 million individuals were enrolled in Medicaid expansion or Marketplace health insurance plans in late 2020/early 2021, the highest total on record. <u>Details</u>.
- **CMS** announced a notice of funding opportunity (NOFO) for Navigators in states with a Federally-Facilitated Marketplace (FFM). <u>Details</u>.

COMMENT & APPLICATION DEADLINES

• 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 <u>Primary Care First Model</u>. <u>Details</u>.
- June 25: The FTC issued a request for public feedback to inform their review of how to best update their approaches to analyzing the effects of pharmaceutical mergers. <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 6: HHS <u>announced</u> that \$14.2 million in funding available to expand access to pediatric mental health care. <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 12: CMS released an <u>interim final rule (IFR) with comment period</u> that revises infection control requirements related to COVID-19 for long-term and intermediate care facilities. <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>.
- July 19: The FDA <u>issued</u> 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). <u>Details</u>.
- August 2: FDA <u>issued</u> draft guidance on oral drug products administered via enteral feeding tube. Comments are due August 2. <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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