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

Wynne Health Group Weekly



FRAMING THE WEEK

The COVID-19 legislative dash continues this week as Democrats aim to pass **President Joe Biden's \$1.9 trillion American Rescue Plan** by March 14, the expiration of temporary federal unemployment benefits. Later today, the House Budget Committee will <u>mark up</u> the <u>package</u> of individual bills approved by various House committees, setting up a House floor vote by Friday or Saturday. The Senate will likely make changes to the anticipated House-approved package as Byrd Rule objections are raised and party leaders work to earn all 50 Democratic votes (particularly those of Sens. Joe Manchin (D-WV) and Kyrsten Sinema (D-AZ)).

After a significant delay, **Xavier Becerra**, **Biden's pick to lead the Department of Health and Human Services**, will appear before the Senate Health, Education, Labor and Pensions Committee (HELP) tomorrow (Feb. 23) and the Senate Finance Committee (SFC) on Wednesday (Feb. 24), both of which will vote to send his nomination to the Senate floor for a final vote. Unlike Neera Tanden, Biden's nominee to head the Office of Management and Budget, Becerra appears on track to be confirmed. Still, Senate Republicans are expected to attack Becerra's record on Medicare for All and abortion rights, among other issues.

On Thursday (Feb. 25), the Senate HELP Committee will consider the nominations of Vivek Murthy to serve as the Surgeon General and Rachel Levin to serve as the Assistant Secretary of Health. Today (Feb. 22), Merrick Garland, Biden's nominee for Attorney General, begins a two-day hearing with the Senate Judiciary Committee. SFC is expected to move "quickly" on the nomination of Chiquita Brooks-LaSure to be the Administrator of the Centers for Medicare and Medicaid Services (CMS).

On Friday (Feb. 26), the Food and Drug Administration's (FDA) Vaccines and Related Biological Products Advisory Committee will discuss emergency use authorization of the single-dose COVID-19 vaccine developed by Johnson & Johnson (J&J). According to their Phase 3 clinical trial, the vaccine is 66 percent effective at preventing moderate to severe COVID symptoms, 85 percent effective in preventing severe cases of the disease, and "demonstrated complete protection against COVID-19 related hospitalization and death," 28 days after vaccination. Unlike Pfizer's and Moderna's vaccines, the J&J vaccine can be stored in most standard refrigerators. J&J announced that they expect to supply the U.S. with 100 million doses in the first half of the year.

Tomorrow (<u>Feb. 23</u>), J&J, Pfizer, Moderna, AstraZeneca, and Novavax (all of whom received funding through Operation Warp Speed) will be questioned by the House Energy and Commerce Subcommittee on Oversight and Investigations about their ongoing efforts to develop and accelerate production of **COVID-19 vaccines** in the U.S. The Senate Veterans Affairs Committee (<u>Feb. 25</u>) and House Ways and Means Committee (<u>Feb. 26</u>) will also convene hearings to discuss COVID-19 vaccination issues this week.

On Wednesday (Feb. 25), the House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies will hear from state officials regarding **public health infrastructure**

issues. The discussion will likely inform the drafting of FY 2022 appropriations legislation. We may see an announcement this week from Appropriations Committee leaders regarding the reintroduction of **earmarks** into the process, which would likely limit them to government agencies and non-profit organizations.

THIS WEEK IN HEALTH POLICY

Mon. (2/22)

- 9:30am Hearing: Attorney General Nomination The Senate Judiciary Committee convenes a hearing to consider the nomination of the Honorable Merrick Brian Garland to be Attorney General of the United States: Day 1. Details.
- **1:00pm Markup: COVID-19** The House Budget Committee convenes a markup of the American Rescue Plan Act of 2021. <u>Details</u>.

Tue. (2/23)

- 10:00am Hearing: HHS Secretary Nomination The Senate Health, Education, Labor and Pensions Committee convenes a hearing to consider the nomination of Xavier Becerra to be Secretary of Health and Human Services. Details.
- 10:00am Hearing: Attorney General Nomination The Senate Judiciary Committee convenes a hearing to consider the nomination of the Honorable Merrick Brian Garland to be Attorney General of the United States: Day 2. Details.
- 10:30am Hearing: COVID-19 Vaccines The House Energy and Commerce Subcommittee on Oversight and Investigations convenes a hearing titled, "Pathway to Protection: Expanding Availability of COVID-19 Vaccines," featuring officials from five manufacturers producing and developing COVID-19 vaccines (AstraZeneca, Johnson & Johnson, Moderna, Novavax, and Pfizer). Details.

Wed. (2/24)

- 10:00am Hearing: Public Health The House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies convenes a hearing titled, "Ready or Not: U.S. Public Health Infrastructure." Details.
- **2:30pm Hearing: HHS Secretary Nomination** The Senate Finance Committee convenes a hearing to consider the nomination of Xavier Becerra to be Secretary of Health and Human Services. Details.
- 3:00pm Hearing: COVID-19 Vaccines for Veterans The Senate Veterans' Affairs Committee convenes a hearing titled, "Vaccines for Vets: Our Best Shot at Ending the COVID-19 Pandemic."
 <u>Details</u>.

Thurs. (2/25)

• 10:00am – Hearing: HHS Nominations – The Senate HELP Committee convenes a hearing to discuss the nominations Vivek Murthy to serve as Medical Director in the Regular Corps of the Public Health Service and Surgeon General of the Public Health Service, and Rachel Levine to serve as Assistant Secretary of Health and Human Services. <u>Details</u>.

Fri. (2/26)

• 9:00am-5:30pm – FDA Meeting: COVID-19 Vaccines – FDA convenes a meeting of the Vaccines and Related Biological Products Advisory Committee to discuss EUA of the Janssen Biotech Inc. COVID-19 Vaccine for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years and older. Details.

- **2:00pm Hearing: COVID-19 Vaccines** The House Ways and Means Subcommittee on Health convenes a hearing titled, "The Path Forward on COVID-19 Immunizations." <u>Details</u>.
- **3:00pm-5:00pm HHS Meeting: COVID-19 and Equity** HHS convenes the first meeting of the COVID-19 Health Equity Task Force (Task Force). <u>Details</u>.

Additional Multi-Day Events

- **February 22-February 24 CDC Forum: COVID-19 Vaccine** CDC hosts the National Forum on COVID-19 vaccine, a multi-day event aimed at advancing the goals of the National Strategy for the COVID-19 Response and Pandemic Preparedness and building trust and confidence in COVID-19 vaccines. Details.
- **February 24-February 25 CDC Meeting: Vaccines** CDC convenes a meeting of the Advisory Committee on Immunization Practices to discuss cholera vaccine, hepatitis B vaccine, influenza vaccines, zoster vaccine, orthopoxvirus vaccine, pneumococcal vaccine, rabies vaccine and tickborne encephalitis vaccine. <u>Details</u>.

FEATURED WHG ANALYSIS

- WHG Issue Brief: No Surprises Act Implementation In the Policy Hub Insight Bank here.
- WHG: Implementation Timeline of the Omnibus Package In the Policy Hub Insight Bank here.
- WHG Legislative and Regulatory Outlook for 2021 In the Policy Hub Insight Bank here.
- WHG: Regulatory Freeze: Key Policies and Dates In the Policy Hub Insight Bank here.
- WHG: Materials Related to COVID-19 Vaccine Confidence In the Policy Hub Insight Bank here.
- WHG Catalogue of COVID-19 Government Response December-January Edition In the Policy Hub Insight Bank here.

CONGRESSIONAL LOOKBACK

Wed. (2/17)

• Sens. Bennet (D-CO) and Kaine (D-VA) <u>reintroduced</u> their public option proposal, the Medicare-X Choice Act of 2021, which would establish a federal public option that is based on Medicare. <u>Details</u>.

REGULATORY LOOKBACK

Thurs. (2/18)

• **HHS** <u>published</u> a notice communicating that the new effective date of its final rule creating a safe harbor to pass manufacturer rebates to the point of sale is now January 1, 2023. <u>Details</u>.

Wed. (2/17)

• The White House <u>announced</u> new actions the administration is taking to expand and improve COVID-19 testing. <u>Details</u>.

Tue. (2/16)

• The USPSTF <u>issued</u> a draft recommendation statement in favor of screening for gestational diabetes mellitus (GMD) in asymptomatic pregnant persons at 24 weeks of gestation or after. Details.

COMMENT & APPLICATION DEADLINES

- **Feb. 22:** HRSA announced a maternal health-focused Notice of Funding Opportunity (NOFO)

 Primary Care Training and Enhancement-Community Prevention and Maternal Health. <u>Details</u>.
- **Feb. 27:** The FDA issued a <u>request for nominations</u> for voting members to serve on the Technical Electronic Product Radiation Safety Standards Committee.
- March 4: The HHS Office of Minority Health is seeking nominations of qualified candidates for appointment to the Advisory Committee on Minority Health. <u>Details</u>.
- March 10: CMS requests comment on proposed changes to the Quality Rating System (QRS) and Qualified Health Plan (QHP) Enrollee survey program. <u>Details</u>.
- March 12: CDC released a <u>request for nominations</u> for membership to the Advisory Committee on Breast Cancer in Young Women.
- March 15: HRSA announced a maternal and child health-focused Notice of Funding Opportunity (NOFO) Early Childhood Comprehensive Systems: Health Integration Prenatal-to-Three Program. Details.
- March 15: The USPSTF <u>issued</u> a draft recommendation statement in favor of screening for gestational diabetes mellitus (GMD) in asymptomatic pregnant persons at 24 weeks of gestation or after. Details.
- March 15: USPSTF <u>announced</u> a request for nominations to serve on the task force. Selected members will serve a four-year term. <u>Details</u>.

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