

Wynne Health Group Weekly



FRAMING THE WEEK

COVID-19

The Biden Administration faces a crucial week, as **President Biden** and top health officials try to ensure public confidence in the administration's COVID-19 response, especially as the Centers for Disease Control and Prevention (CDC) faces harsh criticism over its new isolation and quarantine guidelines for the [general population](#) and [schools](#). The President is scheduled to deliver remarks on the pandemic response on Thursday. Ahead of his speech, we could see the Departments of Health and Human Services (HHS), Labor, and Treasury issue guidance clarifying how individuals who purchase rapid, over-the-counter (OTC) COVID-19 tests can seek reimbursement from their private health insurer. January 15 is the Administration's self-imposed deadline for this guidance, according to an [announcement](#) made in December and [reiterated](#) by Biden last week.

Tomorrow, the Senate Committee on Health, Education, Labor and Pensions (HELP) will question top health officials about the Biden-Harris Administration's response to rising COVID-19 cases fueled by the Omicron variant. The panel features **Dr. Rochelle Walensky**, Director of the CDC; **Dr. Anthony Fauci**, Director of the National Institute of Allergy and Infectious Diseases, National Institutes of Health; **Dr. Janet Woodcock**, Acting Commissioner of the Food and Drug Administration (FDA); and **Dawn O'Connell**, Assistant Secretary for Preparedness and Response. They last appeared before the Senate HELP Committee in early November – when the U.S. was seeing a downward trend in cases, hospitalizations, and deaths after the Delta surge over the summer.

With the new reality settling in that COVID-19 is not going away – and negotiations over the Build Back Better bill on pause – we could see lawmakers refocus their energy on legislation to bolster the federal COVID-19 response. **Committee Chair Patty Murray (D-WA)** and **Ranking Member Richard Burr (R-NC)** may soon release their highly anticipated bipartisan pandemic preparedness bill. According to a plan [outlined](#) in April 2021, the legislation would include highly needed resources and strategies to strengthen public health infrastructure and medical capacity, countermeasure development, and medical supply chains.

FDA

On Wednesday, the Senate HELP Committee will consider the [nomination](#) of **Dr. Robert Califf** to serve as the FDA Commissioner. Dr. Califf led the FDA during the last year of the Obama Administration and was confirmed with strong, bipartisan support in 2016 ([89-4-7](#)). We anticipate Dr. Califf will clear the Senate HELP Committee and be approved by the full Senate, despite some opposition from lawmakers – including Sens. Joe Manchin (D-WV) and Bernie Sanders (I-VT) – over his ties to the pharmaceutical industry. At his confirmation hearing in December, Dr. Califf [said](#) his priorities would be:

- Strengthening the FDA's emergency preparedness and response infrastructure;
- Protecting consumers and patients (e.g., systematic approaches to evaluating benefits and risks of medical products, ensuring food safety, protecting kids from tobacco products, and reducing overdose deaths); and
- Modernization and innovation.

Medicare

Later this week, the Medicare Payment Advisory Commission will review and vote on draft Medicare fee-for-service (FFS) payment updates for the March 2022 Report to Congress. Commissioners will also [discuss](#) the following:

- A congressionally requested report on a new value-incentive program for post-acute care (due March 15, 2022);
- A status report on dual-eligible special needs plans;
- A status report on the Medicare prescription drug program (Part D); and
- A multi-track population-based payment model with administratively updated benchmarks (as part of their work on streamlining and harmonizing advanced alternative payment models).

THIS WEEK IN HEALTH POLICY

Tue. (1/11)

- **10:00am – Hearing: COVID-19 Variants** – The Senate Health, Education, Labor & Pensions (HELP) Committee holds a hearing titled, “Addressing New Variants: A Federal Perspective on the COVID-19 Response.” [Details](#).

Wed. (1/12)

- **10:00am – CDC Meeting: Immunization** – The Centers for Disease Control and Prevention (CDC) holds a meeting of the Advisory Committee on Immunization Practices (ACIP) to discuss the cholera vaccine, tick-borne encephalitis vaccine, influenza vaccines, hepatitis vaccines, and respiratory syncytial virus vaccine. [Details](#).

Additional Multi-Day Events

- **January 13-January 14 – MedPAC Meeting** – The Medicare Payment Advisory Commission to discuss Medicare issues and policy questions. [Details](#).

FEATURED WHG ANALYSIS

- **WHG Issue Brief on Health Equity Implications of Potential Telehealth Reform Under Medicare** – In the Policy Hub Insight Bank [here](#).
- **WHG Side-by-Side of Live Drug Pricing Proposals Under Consideration for Reconciliation** – In the Policy Hub Insight Bank [here](#).
- **WHG Side-by-Side of Medicaid Expansion Gap Bills** – In the Policy Hub Insight Bank [here](#).
- **WHG Side-by-Side of Health Technology Assessment Models** – In the Policy Hub Insight Bank [here](#).
- **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](#).

REGULATORY LOOKBACK

Fri. (1/7)

- **CMS** is seeking [nominations](#) for a Technical Expert Panel (TEP) related to the development of additional quality measures for the SNF VBP program as mandated by the CAA. Nominations are due January 16. [Details](#).

- **CMS [announced](#)** a new Healthcare Common Procedure Coding System (HCPCS) code for VEKLURY™ (remdesivir) antiviral medication. [Details](#).
- **The USDA [announced](#)** an adjustment to school meal reimbursement to account for inflation that will put an additional \$750 million into school meal programs. [Details](#).

Thurs. (1/6)

- **CMS [released](#)** the Contract Year (CY) 2023 Policy and Technical Changes to Medicare Advantage (MA) and Part D proposed rule. Comments are due March 7. [Details](#).
- **The Treasury Department** issued the [final rule](#) for the [State and Local Fiscal Recovery Funds \(SLFRF\) program](#) established by the American Rescue Plan Act of 2021. [Details](#).
- **MACPAC [published](#)** an issue brief examining medical loss ratio (MLR) for Medicaid managed care organizations (MCOs). [Details](#).
- **HRSA [released](#)** a notice of funding opportunity (NOFO) for the Rural Public Health Workforce Training Network (RPHWTN) Program. Applications are due March 18. [Details](#).
- **CMS** approved three California State Plan Amendments (SPAs) implementing temporary policies during the period of the COVID-19 public health emergency (PHE). [Details](#).

Wed. (1/5)

- **HHS [announced](#)** a tenth amendment to its March 2020 Declaration under PREP Act to expand access to seasonal influenza vaccines. [Details](#).

Tues. (1/4)

- **ASPE [published](#)** the 2021 update to the National Plan to Address Alzheimer's Disease. [Details](#).
- **ASPE** released reports ([here](#) and [here](#)) assessing the certified community behavioral health clinics (CCBHC) demonstration program. [Details](#).
- **CMS** issued [guidance](#) on the scope of and payments for qualifying community-based mobile crisis intervention services authorized by the ARP. [Details](#).

Mon. (1/3)

- **CMS** released the 2023 HHS Notice of Benefit Payment Parameters [proposed rule](#). Comments are due January 27. [Details](#).
- **CMS [issued](#)** a final rule to rescind the Most Favored Nation (MFN) model. [Details](#).

COMMENT & APPLICATION DEADLINES

- **January 16:** CMS is seeking [nominations](#) for a Technical Expert Panel (TEP) related to the development of additional quality measures for the SNF VBP program as mandated by the CAA. [Details](#).
- **January 18:** The FDA issued a [proposed rule](#) and [draft guidance](#) to improve access to hearing aids through the establishment of an over-the-counter (OTC) hearing aid category. [Details](#).
- **January 21:** The FDA [issued](#) draft guidance on data standards for drug and biological product submissions containing real-world data (RWD). [Details](#).
- **January 24:** HHS, DOL, the Treasury, and OPM [issued](#) an IFC to implement the health insurance plan reporting requirements on prescription drug and health care spending. [Details](#).
- **January 25:** NIOSH published a [notice](#) extending the public comment period for the previously announced request for information (RFI) on interventions to support health worker mental health. [Details](#).
- **January 27:** CMS released the 2023 HHS Notice of Benefit Payment Parameters [proposed rule](#). [Details](#).
- **February 2:** The FDA [issued](#) draft guidance on content of premarket submissions for device software functions. [Details](#).
- **February 15:** The FDA [issued](#) a request for nominations for voting members to serve on the Medical Devices Advisory Committee device panels. [Details](#).

- **February 22:** The USDA [announced](#) \$1.15 billion in grant funding for rural broadband access. [Details.](#)
- **March 7:** CMS [released](#) the Contract Year (CY) 2023 Policy and Technical Changes to Medicare Advantage (MA) and Part D proposed rule. [Details.](#)
- **March 18:** HRSA [released](#) a notice of funding opportunity (NOFO) for the Rural Public Health Workforce Training Network (RPHWTN) Program. [Details.](#)
- **April 22:** The NIH [announced](#) a \$1 million prize competition for innovative diagnostics technologies to help improve maternal health. [Details.](#)

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