

*Wynne Health Group Weekly*



**FRAMING THE WEEK**

As the Biden-Harris Administration takes office this week, transforming the nation's **COVID-19 pandemic response** is one of their top priorities, along with addressing the economic downturn, the climate crisis, and systemic racism. Over his first several days in office, President-elect Joe Biden is expected to sign a series of executive orders, including a national mask mandate on federal property and during interstate travel. Biden will take additional actions to address the reopening of schools and businesses through expanded testing, worker protections, and clear public health standards.

While the Trump-Pence Administration deferred responsibility for managing COVID-19 testing and vaccination to states, the incoming administration is expected to take a more hands-on approach. To help meet their "goal of 100 million shots by the end of our first 100 days," the Biden-Harris administration will launch a **national vaccination program**, encourage states to allow more people to be vaccinated, including individuals 65 and older as well as frontline workers; and invoke the **Defense Production Act** to ensure sufficient supplies; among other actions outlined in their [COVID-19 vaccination plan](#).

Securing the federal funding needed to fully operationalize such a response plan is likely to face some pushback on Capitol, as the \$400 billion proposed by Biden to address COVID-19 (including \$160 billion for the national vaccination program), is wrapped into a \$1.9 trillion package, an overall price tag that is likely too great for Republicans. Biden's "[America Rescue Plan](#)," the first of a two-step legislative proposal, also includes measures to expand access to health coverage, including subsidizing COBRA coverage through September, increasing the value of advanced premium tax credits, and expanding those subsidies above the existing 400 percent of poverty threshold by capping health insurance premiums at 8.5 percent of income. Biden's ability to earn bipartisan support for his expansive rescue plan will test his deal-making skills. If those efforts fail, we expect Democrats to turn to the reconciliation process to move policies that are eligible for that mechanism forward.

An overview of health policy events of interest in the coming week is included below for your convenience.

**THIS WEEK IN HEALTH POLICY**

**Wed. (1/20)**

- **11:00am – Inauguration** – President-elect Joe Biden and Vice President-elect Kamala Harris will be sworn into office.

**FEATURED WHG ANALYSIS**

- **WHG Catalogue of COVID-19 Government Response** – November Edition – In the Policy Hub Insight Bank [here](#).
- **California v. Texas: Analysis of Supreme Court Oral Arguments** – In the Policy Hub Insight Bank [here](#).

## CONGRESSIONAL LOOKBACK

### Fri. (1/15)

- **MedPAC** convened virtually for Day Two of its January public meeting, hosting sessions on Medicare Part D, skilled nursing facility value-based purchasing program, and Medicare's vaccine coverage and payment policies. [Details](#).

### Thurs. (1/14)

- **MedPAC** convened virtually for Day One of its January public meeting, hosting sessions on Medicare payment policies, alternative payment models, and telehealth. [Details](#).

### Mon. (1/11)

- **The House Ways and Means Committee** [unveiled](#) a new legislative framework for how the Committee will address the role that racism, ableism, and other social, structural, and political determinants have in perpetuating health and economic inequity in the United States. [Details](#).

## REGULATORY LOOKBACK

### Fri. (1/15)

- **CMS** [released](#) the Contract Year (CY) 2022 Medicare Advantage (MA) and Part D Final Rule to address the remaining proposals from the February 2020 proposed rule. [Details](#).
- **HRSA** recently announced a rural health-focused Notice of Funding Opportunity (NOFO) – Evidence Based Telehealth Network Program. Applications are due April 2, 2021. [Details](#).
- **HHS** announced reporting updates for the Provider Relief Fund (PRF). [Details](#).
- **CMS** issued a [final rule](#) implementing new interoperability requirements for the exchange of patient health care data between CMS-regulated payers. [Details](#).

### Thurs. (1/14)

- **CMS** released the 2022 Notice of Benefit and Payment Parameters [final rule](#) ([press release](#); [fact sheet](#)), finalizing a subset of originally proposed policies affecting Exchanges and plans in the individual and small group markets. [Details](#).
- **AHRQ** [issued](#) a request for scientific information submissions to inform its review on Interventional Treatments for Acute and Chronic Pain: Systematic Review. Submissions are due February 14. [Details](#).
- **FDA** [announced](#) that it is permanently waiving the premarket notification requirements 7 class I devices for which the 510(k) requirements had been temporarily waived for the COVID-19 pandemic. The agency is also proposing to permanently exempt 84 additional devices from 510(k) premarket requirements and is seeking public comment on whether all or some of the devices should be exempted. Comments are due March 16. [Details](#).
- **The Rural Housing Service** recently announced it is now accepting applications for fiscal year (FY) 2021 of the Community Facilities Technical Assistance and Training (TAT) Grant program. Applications are due by March 29, 2021. [Details](#).
- **HHS** published a final rule ([press release](#)) requiring certain transparency standards when the department seeks to take civil enforcement actions against regulated parties. [Details](#).
- **HRSA** recently announced a maternal and child health-focused Notice of Funding Opportunity (NOFO) – Autism Secondary Data Analysis Research (SDAR) Program. Applications are due April 12, 2021. [Details](#).

- CMS published a [document](#) in the Federal Register public inspection documents formally withdrawing from CMS' regulatory agenda the Medicaid Fiscal Accountability Regulation proposed rule, published on November 18, 2019. [Details](#).

### **Wed. (1/13)**

- CMS launched a new [web-based platform](#) for Section 1135 waiver requests ([press release](#)). The new platform enables streamlined documentation and centralizes requests, which CMS asserts will reduce regulatory burden and improve responsiveness. [Details](#).
- ONC released the Draft United States Core Data for Interoperability Version 2 ([Draft USCDI v2](#)). The Draft USCDI v2 makes updates to the existing set of health data classes and data elements for interoperable health information exchange. Comments on the draft are due by April 15, 2021. [Details](#).
- CMS recently issued [guidance](#) to state health officials designed to drive the adoption of strategies that address the social determinants of health (SDOH) in Medicaid and the Children's Health Insurance Program (CHIP). [Details](#).
- CMS issued its final enrollment snapshot ([press release](#)) on ACA Marketplace sign-ups for 2021 Open Enrollment. [Details](#).

### **Tues. (1/12)**

- CMS finalized a rule establishing a new pathway for expedited coverage of innovative medical devices. [Details](#).
- NIH [issued](#) several funding opportunities announcements (FOAs) out of the Helping to End Addiction Long-term (HEAL) Initiative. [Details](#).
- HHS announced it has developed a [web-based locator](#) for COVID-19 outpatient treatment sites offering monoclonal antibody therapeutics. [Details](#).
- HHS reported on findings from a recent study showing that rates of pregnant women with opioid use disorder (OUD) and babies born with withdrawal symptoms increased between the years of 2010 and 2017. [Details](#).
- HRSA announced a maternal and child health-focused Notice of Funding Opportunity (NOFO) – Emerging Issues in Maternal and Child Health. Applications are due April 9, 2021. [Details](#).
- HRSA released a rural health-focused Notice of Funding Opportunity (NOFO) – Rural Communities Opioid Response Program -Psychostimulant Support (RCORP-PS). Applications are due April 12, 2021. [Details](#).

### **Mon. (1/11)**

- NIH [released](#) findings from a study that examined collaborative physician-pharmacist management of opioid addiction treatment. The study aimed to address the treatment access barrier that many underserved communities face when receiving buprenorphine. [Details](#).
- HHS Secretary Alex Azar [announced](#) that the FDA will annually publish certain information regarding the time required for agency review and approval of New Drug Applications (NDAs) and Abbreviated New Drug Applications (ANDAs). [Details](#).
- CMS recently [approved](#) a Section 1115 Medicaid [waiver](#), for the state of Tennessee that would allow the state to implement an “aggregate cap” financing model in its Medicaid program. [Details](#).

### **COMMENT & APPLICATION DEADLINES**

- **Jan. 21:** HRSA announced a Notice of Funding Opportunity for the Behavioral Health Workforce Education and Training (BHWET) Program for Professionals for FY 2021. [Details](#).

- **Jan. 27:** GAO issued a request for nominations for the State All Payer Claims Databases Advisory Committee. [Details.](#)
- **Jan. 26:** CMS [issued](#) an interim final rule with comment period (IFC) to implement the Most Favored Nation (MFN) Model, pursuant to President Trump’s [executive order](#) (EO) on Lowering Drug Prices by Putting America First. [Details.](#)
- **Feb. 5:** CMS issued a [call for public comment](#) on which episode-based cost measures to develop for the next wave of Merit-Based Incentive Payment System (MIPS) measures. The measures developed during this wave could impact performance-based Medicare payment adjustments for MIPS-eligible clinicians for CY 2022 or CY 2023. [Details.](#)
- **Feb. 7:** FDA [announced](#) a request for nominations for consumer representatives to serve on several advisory committees and panels. [Details.](#)
- **Feb. 7:** FDA [announced](#) a request for nominations for the National Mammography Quality Assurance Advisory Committee in the Center for Devices and Radiological Health. The FDA is also soliciting industry organizations that are interested in participating in the selection of nonvoting members for the Committee. [Details.](#)
- **Feb. 12:** OHRP is seeking nominations of qualified candidates for appointment to the Secretary’s Advisory Committee on Human Research Protections. [Details.](#)
- **Feb. 12:** FEMA seeks comments on a [proposed rule](#) to revise the “Estimated cost of the assistance,” which is one of the factors FEMA’s Public Assistance Program considers when evaluating requests from states for major disaster declarations and making recommendations to the President. [Details.](#)
- **Feb. 16:** CMS seeks comment on plans for a new Review Choice Demonstration for inpatient rehabilitation facility (IRF) services. [Details.](#)
- **Feb. 19:** FDA [announced](#) a request for nominations for members to serve on the National Mammography Quality Assurance Advisory Committee in the Center for Devices and Radiological Health. [Details.](#)
- **Feb. 22:** HRSA announced a maternal health-focused Notice of Funding Opportunity (NOFO) – Primary Care Training and Enhancement-Community Prevention and Maternal Health. [Details.](#)
- **Feb. 27:** The FDA issued a [request for nominations](#) 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. [Details.](#)
- **March 12:** CDC released a [request for nominations](#) 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:** USPSTF [announced](#) a request for nominations to serve on the task force. Selected members will serve a four-year term. [Details.](#)

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