

*Wynne Health Group Weekly*



**FRAMING THE WEEK**

Congressional leaders have made progress in their attempts to negotiate a **coronavirus relief bill** that they intend to combine with the fiscal year 2021 omnibus spending package. Lawmakers are expected to pass a one-week stopgap measure through December 18 to give negotiators more time, as a slew of issues still need to be ironed out. Legislative text for the bipartisan \$908 billion coronavirus relief proposal floated last week is anticipated to be released “early this week,” [according](#) to Sen. Bill Cassidy (R-LA) who also said that President Trump indicated he will sign their proposal.

**President-elect Biden** also [weighed in](#) on relief talks, urging lawmakers and President Trump to “act now.” He said he was “encouraged” by the bipartisan \$908 billion proposal offered by centrist senators and called on Congress to provide “more economic relief as a bridge through 2021 until both the pandemic and economic crises are over.”

The inclusion of a **surprise billing policy** in the relief bill was discussed in earnest by staff over the weekend. House Speaker Nancy Pelosi (D-CA) is very interested in including this policy in the relief bill, but Ways and Means Chairman Richard Neal (D-MA) would prefer to wait until next Congress in order to give President-elect Biden a policy victory. Proponents and opponents are weighing in with congressional leaders this week as the talks heat up.

In other transition-related news, Biden [chose](#) California Attorney General Xavier Becerra for **Department of Health and Human Services (HHS) Secretary** and Dr. Rochelle Walensky, an infectious-disease specialist at Massachusetts General Hospital, for the Director of the **Centers for Disease Control and Prevention (CDC)**. Notably, Becerra is leading the defense of the Affordable Care Act before the Supreme Court in *Texas v. Azar*. Dr. Vivek Murthy was tapped to serve as **Surgeon General**, a role he held under the Obama administration.

As access to a **COVID-19 vaccine** nears, at least for a key segment of the U.S. population, additional funding for states to assist with vaccine distribution remains a bipartisan issue. The \$908 billion bipartisan proposal includes \$16 billion for vaccine development and distribution, as well as testing and contact tracing. Senate Majority Leader Mitch McConnell’s (R-KY) revised proposal provides \$31 billion to support vaccine distribution, along with vaccine, therapeutic and diagnostic development, the Strategic National Stockpile, and grants to establish state stockpiles.

On Thursday (December 10), the **Vaccines and Related Biological Products Advisory Committee** will [discuss](#) emergency use authorization of the Pfizer-BioNTech COVID-19 vaccine for individuals 16 years of age and older. Upon emergency use authorization by the Food and Drug Administration (FDA), which could occur shortly after the meeting, Pfizer’s vaccine could be distributed within 24 hours and administered to priority patients within days. Last week, Dr. Robert Redfield, Director of the CDC, [signed off](#) on interim recommendations approved by the Advisory Committee on Immunization Practices (ACIP)

to offer the authorized COVID-19 vaccine to both (1) health care personnel and (2) residents of long-term care facilities in the initial phase of the vaccination program.

On the regulatory front, HHS has largely finished its annual payment update rulemaking cycle with the recent release of the CY 2021 Physician Fee Schedule ([details](#)) and Hospital Outpatient Prospective Payment Systems ([details](#)). However, a number of new rules have recently arrived at OMB for review, including a [final rule](#) on administrative dispute resolution for the **340B program**, as well as a [proposed rule](#) regarding **patient access to electronic health information**. A [final rule](#) that would implement the Trump administration's recent drug pricing executive order to offer insulin and **injectable epinephrine** at lower prices for patients visiting 340B facilities ([details](#)) has also arrived for review.

The **Medicaid and CHIP Payment and Access Commission (MACPAC)** convenes later this week (December 10 and 11) to resume [discussions](#) on improving health equity, extending postpartum coverage, and increasing access to behavioral health services for children and adolescents. Commissioners are also slated to discuss a draft recommendation relating to Medicaid estate recovery, the interim final rule affecting Medicaid provisions of the Families First Coronavirus Relief Act, and implications of the 2020 elections, among other topics.

An overview of health policy events of interest in the coming week is posted to [Policy Hub](#) and included below for your convenience.

## **THIS WEEK IN HEALTH POLICY**

### **Tue. (12/8)**

- **10:00am – Hearing: Abortion Access** – The House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies convenes a hearing titled, “The Impact on Women Seeking an Abortion but are Denied Because of an Inability to Pay.” [Details.](#)
- **10:00am-1:15pm – HHS Meeting: Physician Payment** – HHS convenes a meeting of the Physician-Focused Payment Model Technical Advisory Committee to discuss the role telehealth can play in optimizing health care delivery and value-based transformation in the context of alternative payment models (APMs) and PFPs specifically. [Details.](#)

### **Wed. (12/9)**

- **1:00pm-2:00pm – CMS Webinar: ESRD** – CMS hosts an introductory webinar to help ESRD Treatment Choices (ETC) Model Participants prepare for the ETC Model. [Details.](#)

### **Thurs. (12/10)**

- **9:00am-6:00pm – FDA Meeting: COVID-19 Vaccine** – FDA convenes a meeting of the Vaccines and Related Biological Products Advisory Committee to discuss Emergency Use Authorization (EUA) of the Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 in individuals 16 years of age and older. [Details.](#)
- **TBD – MACPAC: Day 1** – The Medicaid and CHIP Payment and Access Commission (MACPAC) convenes a virtual public meeting to discuss Medicaid and CHIP payment and policy issues. [Details.](#)

### **Fri. (12/11)**

- **TBD – MACPAC: Day 2** – MACPAC convenes a virtual public meeting to discuss Medicaid and CHIP payment and policy issues. [Details.](#)

## 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](#).
- **WHG Issue Brief: COVID-19 Vaccine State of Play** – In the Policy Hub Insight Bank [here](#).

## CONGRESSIONAL LOOKBACK

### Fri. (12/4)

- **MedPAC** concluded its December virtual [public meeting](#) at which it considered a series of draft payment update recommendations for Medicare payment systems in 2022 for inclusion in its March 2021 Report to Congress. The Commission will formally vote on the recommendations at its next public meeting, scheduled for January 14-15, 2021. [Details](#).

## REGULATORY LOOKBACK

### Fri. (12/4)

- **HHS** [released](#) its [final rule](#) governing the agency's release and maintenance of guidance documents. The final rule clarifies HHS' obligations under the Administrative Procedure Act and improves how the Department issues and maintains guidance documents to ensure appropriate notice of new guidance and protect regulated entities from obligations not already reflected in statutes or regulations. [Details](#).
- **The HHS Office of Minority Health** [announced](#) that it is seeking nominations of qualified candidates for appointment to the Advisory Committee on Minority Health. Nominations are due March 4, 2021. [Details](#).

### Thurs. (12/3)

- **HHS** [released](#) an [Action Plan](#) and announced a partnership with the March of Dimes to address the disparity gap in maternal health outcomes for black women through the implementation of evidence-based best practices to improve healthcare quality in hospital settings. [Details](#).
- **FDA** [issued](#) final guidance on requesting FDA feedback on combination products. The guidance is intended to provide ways in which combination product sponsors can obtain feedback from the agency on scientific and regulatory questions. [Details](#).
- **HHS** [issued](#) an amendment to the Public Readiness and Emergency Preparedness (PREP) Act to increase access to covered countermeasures during the COVID-19 public health emergency (PHE). [Details](#).

### Wed. (12/2)

- **CMS** [released](#) the calendar year (CY) 2021 hospital outpatient prospective payment system (OPPS) [final rule](#) with comment period addressing payments to hospital outpatient departments and ambulatory surgery centers (ASCs). [Details](#).
- **HHS OIG** [posted](#) its Semiannual Report to Congress for the six month period ending September 30, 2020. [Details](#).

### Tue. (12/1)

- **CMS** released the calendar year (CY) 2021 Medicare Physician Fee Schedule (MPFS) [final rule](#) ([fact sheet](#)), which addresses an array of policies under Medicare Part B and the Medicare Access and CHIP Reauthorization Act (MACRA) Quality Payment Program (QPP). [Details](#).

- **OASH** [announced](#) a request for information on its draft HIV National Strategic Plan: A Roadmap to End the HIV Epidemic (2021-2025). Comments are due December 12. [Details](#).
- **AHRQ** [announced](#) a request for scientific information submissions to inform its review on Models of Care that Include Primary Care for Adult Survivors of Childhood Cancer. Submissions are due December 25. [Details](#).

#### **Mon. (11/30)**

- **AHRQ** [announced](#) a request for scientific information submissions to inform its review on Transitions of Care from Pediatric to Adult Services for Children with Special Healthcare Needs. Submissions are due January 1. [Details](#).

#### **Weds. (11/25)**

- **CMS** released the 2022 Notice of Benefit and Payment Parameters [proposed rule](#), a wide-ranging rule affecting Exchanges and plans in the individual and small group markets. Comments are due on December 30, 2020. [Details](#).
- **HHS** issued a [request for information](#) (RFI) seeking comments on the regulatory relief actions it has taken to respond to the COVID-19 pandemic's impact on the health care industry. Comments are due December 28. [Details](#).

#### **Tues. (11/24)**

- **CMS** issued a [final rule](#) to amend the Department of Health and Human Services' ACA risk adjustment data validation (HHS-RADV) program. [Details](#).
- **HHS** issued a [request for information](#) (RFI) to better understand the effects of the steps taken by health care systems and health care providers to respond to the COVID-19 pandemic. Comments are due by December 24. [Details](#).

#### **COMMENT & APPLICATION DEADLINES**

- **Dec. 11:** AHRQ seeks scientific information submissions to inform its review on Malnutrition in Hospitalized Adults. [Details](#).
- **Dec. 12:** OASH [announced](#) a request for information on its draft HIV National Strategic Plan: A Roadmap to End the HIV Epidemic (2021-2025). [Details](#).
- **Dec. 14:** NIOSH [announced](#) a request for information regarding the use of "elastomeric half-mask respirators" healthcare settings during the COVID-19 pandemic. [Details](#).
- **Dec. 14:** HHS issued a [proposed rule](#) that would add a Smallpox Countermeasures Injury Table for designated covered smallpox countermeasures. [Details](#).
- **Dec. 14:** FDA requests nominations for voting members to serve on the Device Good Manufacturing Practice Advisory Committee (DGMPAC) and the Medical Devices Advisory Committee (MDAC) device panels in the Center for Devices and Radiological Health. [Details](#).
- **Dec. 18:** HHS [announced](#) a request for information (RFI) regarding research integrity and the responsible conduct of research. [Details](#).
- **Dec. 22:** OASH is [soliciting](#) information to better understand what steps stakeholders are taking to transform chronic disease management for conditions such as hypertension, chronic lower respiratory disorders, and cognitive impairment, among aging populations in underserved areas. [Details](#).
- **Dec. 24:** HHS issued a [request for information](#) (RFI) to better understand the effects of the steps taken by health care systems and health care providers to respond to the COVID-19 pandemic. [Details](#).
- **Dec. 25:** AHRQ requests scientific information submissions to inform its review on Models of Care that Include Primary Care for Adult Survivors of Childhood Cancer. [Details](#).

- **Dec. 28:** HHS issued a [request for information](#) (RFI) seeking comments on the regulatory relief actions it has taken to respond to the COVID-19 pandemic’s impact on the health care industry. [Details.](#)
- **Dec. 30:** CMS seeks comment on the 2022 Notice of Benefit and Payment Parameters. [Details.](#)
- **Jan. 1:** FDA seeks comment on draft guidance on cross labeling oncology drugs in combination regimens. [Details.](#)
- **Jan 1:** AHRQ requests scientific information submissions to inform its review on Transitions of Care from Pediatric to Adult Services for Children with Special Healthcare Needs. [Details.](#)
- **Jan. 4:** FDA seeks comments on a proposal to publish a summary of the FDA’s review of Risk Evaluation and Mitigation Strategy (REMS) assessments. [Details.](#)
- **Jan. 5:** CDC announced a funding opportunity for “PrEP Choice: Increasing the Use of HIV Pre-exposure Prophylaxis in an Era of Choices.” The application deadline is January 5, 2021. [Details.](#)
- **Jan. 18:** CMS announced that the Community Health Access and Rural Transformation (CHART) [model](#) is open for applications. Letters of intent are due by January 18, 2021. [Details.](#)
- **Jan 19:** FDA seeks comment on draft guidance entitled “Biosimilarity and Interchangeability: Additional Draft Q&As on Biosimilar Development and the Biologics Price Competition and Innovation (BPCI) Act.” [Details.](#)
- **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. 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.](#)

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