

*Wynne Health Group Weekly*



**FRAMING THE WEEK**

As the first COVID-19 vaccine begins to roll-out across the nation, negotiations on a coronavirus relief deal packaged with fiscal year (FY) 2021 spending step into overdrive as lawmakers now have until Friday of this week before government funding runs dry. President Trump is calling for another round of stimulus payments, which are not included in the \$908 billion bipartisan moderate Senate package that is serving as the base of negotiations. Meanwhile, in a sign that their entire package may not be palatable, this bill is expected to be introduced today but in 2 separate bills that carve the more controversial state and local funding and liability provisions into a separate vehicle.

Lawmakers announced on Friday of last week that they had come to an agreement on **surprise medical billing**. The logjam broke free in these negotiations as House Ways and Means Chairman Richard Neal, D-MA, agreed to changes that push the policy closer to the hospitals and the insurers arbitration position. The policy is to be included in the FY 2021 spending bill and could be used to offset a longer Medicare extenders fix of up to 3 years. While this brings the health care committee leaders and Speaker Pelosi together on one policy, Senator McConnell has not yet signaled his support for this surprise medical billing policy.

On Wednesday, the Senate Finance Subcommittee on Health Care will convene a [hearing](#) to examine **Alzheimer's disease** therapies and diagnostics and discuss the fiscal implications of the disease on Medicare spending. Sens. Pat Toomey (R-PA) and Debbie Stabenow (D-MI), the Chairman and Ranking Member of the Health Care Subcommittee, have teamed up to develop legislation to address Alzheimer's disease. In February, the duo [sought](#) feedback from stakeholders on policy solutions targeting an array of issues, including care coordination; screening and diagnosis; access to long-term care coverage; oversight of nursing homes, home health agencies, and hospices; and innovative treatments and cures. They followed up with a [letter](#) to Health and Human Services (HHS) Secretary Alex Azar in October, urging the Secretary to implement their recommendations through regulatory action. The hearing will likely inform legislation to be introduced next Congress.

On Thursday (December 17), the **Vaccines and Related Biological Products Advisory Committee (VRBAC)** will [discuss](#) emergency use authorization of the Moderna COVID-19 vaccine for individuals 18 years of age and older. Upon emergency use authorization by the Food and Drug Administration (FDA), which could occur shortly after the meeting, Moderna vaccine could be distributed within 24 hours and administered within days to health care workers and nursing home residents. Last week, VRBAC approved a recommendation for the FDA to grant EUA to Pfizer's COVID-19 vaccine. The vaccine is authorized for individuals 16 years and older and Operation Warp Speed officials have stated that all 636 vaccination sites are to receive their first vaccine doses by Wednesday, December 16.

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

**THIS WEEK IN HEALTH POLICY**

### Wed. (12/16)

- **1:00pm-1:30pm – CMS Webinar: SUPPORT Act** – CMS hosts a webinar to provide a brief overview of the expanded reporting requirements going into effect on January 1, 2021 as a result of the SUPPORT Act and regulatory changes and share tips on how to prepare for successful compliance. [Details](#).
- **2:30pm – Hearing: Alzheimer’s Disease** – The Senate Finance Subcommittee on Health Care convenes a hearing titled, “The Alzheimer’s Crisis: Examining Testing and Treatment Pipelines and Fiscal Implications.” [Details](#).

### Thurs. (12/17)

- **9:00am-6:00pm – FDA Meeting: COVID-19 Vaccine** – FDA convenes a meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) to discuss Emergency Use Authorization (EUA) of the Moderna, Inc., COVID-19 Vaccine for the prevention of COVID-19 in individuals 18 years and older. [Details](#).

### Additional Multi-Day Events

- **December 15-December 16 – CMS Town Hall: IPPS** – CMS hosts a town hall meeting to discuss FY 2022 applications for add-on payments for new medical services and technologies under the hospital inpatient prospective payment system (IPPS). [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](#).

### CONGRESSIONAL LOOKBACK

#### Fri. (12/11)

- **MACPAC** convened for Day 2 of its December virtual public meeting and held sessions on access to behavioral health services for children and adolescents; implications of the 2020 Elections for Medicaid policy; the quality rating system in Medicaid Managed Care; and the development of nursing facility payment methods. WHG session summaries are available on Policy Hub [here](#).

#### Thurs. (12/10)

- **MACPAC** convened for Day 1 of its December virtual public meeting and held sessions on: the role of Medicaid in improving health equity; optional and mandatory options for extending postpartum coverage; provisions of the Families First Coronavirus Response Act; countercyclical Medicaid financing adjustments; and integrating behavioral health and clinical care. WHG session summaries are available on Policy Hub [here](#).

#### Wed. (12/9)

- **CBO** released the latest edition of its periodic report, [Options for Reducing the Deficit: 2021 to 2030](#). The report describes 83 policy options that would decrease federal spending or increase federal revenues over the next decade. [Details](#).

- **The House** voted 343 to 67 to approve [H.R. 8900](#), a continuing resolution to extend federal government funding through December 18, 2020 – one week further than the existing expiration date of Friday, December 11. [Details](#).
- **The House of Representatives** passed four bipartisan health care bills, including: The Beneficiary Enrollment Notification and the Eligibility Simplification (BENES) Act of 2019; The Medical Marijuana Research Act of 2019; The “Removing Barriers to Colorectal Screening Act; and HR 7898, which pertains to information blocking. [Details](#).

## REGULATORY LOOKBACK

### Fri. (12/11)

- **HHS OCR** issued a [proposed rule](#) that would modify HIPAA privacy standards for individually identifiable health information. Comments will be due 60 days following publication of the rule. [Details](#).
- **CMS** released a proposed rule outlining additional interoperability proposals for patient health care data between CMS-regulated payers. Comments are due by January 4, 2021. [Details](#).
- **HHS and the Treasury** issued a [final rule](#) to provide greater latitude for grandfathered group health plans and grandfathered group health insurance coverage to increase cost-sharing while preserving their grandfather status. [Details](#).

### Thurs. (12/10)

- **CDC** announced a grant opportunity aimed at increasing COVID-19 and flu vaccination coverage in racial and ethnic populations experiencing disparities in vaccination rates. The application deadline is January 4, 2021. [Details](#).
- **HRSA** issued a [final rule](#) to establish a 340B Drug Pricing Program administrative dispute resolution (ADR) process. [Details](#).

### Tue. (12/8)

- **USPSTF** [issued](#) a draft recommendation and evidence review that recommends clinicians offer pregnant persons recurring behavioral counseling interventions aimed at promoting healthy weight gain and preventing excess gestational weight gain (GWG) in pregnancy. Comments are due January 11. [Details](#).

### Mon. (12/7)

- **HRSA** [announced](#) it is distributing \$523 million in second-round performance payments to more than 9,000 nursing homes in accordance with the HHS plan for Provider Relief Fund performance-based incentive payments. The payments are intended to reward nursing homes for successfully reducing COVID-19 related infections and deaths. [Details](#).
- **HRSA** [announced](#) that it is seeking nominations of qualified candidates for appointment to the National Advisory Council on Migrant Health (NACMH). Nominations will be accepted on a rolling, continuous basis. [Details](#).
- **CMS** released an [Informational Bulletin](#) to states to clarify current federal regulations and expectations for completing redeterminations of eligibility for Medicaid and CHIP beneficiaries. [Details](#).

## COMMENT & APPLICATION DEADLINES

- **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. 4:** CMS released a proposed rule outlining additional interoperability proposals for patient health care data between CMS-regulated payers. [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. 11:** USPSTF [issued](#) a draft recommendation and evidence review that recommends clinicians offer pregnant persons recurring behavioral counseling interventions aimed at promoting healthy weight gain and preventing excess gestational weight gain (GWG) in pregnancy. [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.](#)
- **March 4:** The HHS Office of Minority Health is seeking nominations of qualified candidates for appointment to the Advisory Committee on Minority Health. [Details.](#)

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